

US3462116 (Prod: Crisor, LLC)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:41:32

All time stamps listed in this document are displayed in GMT

US3462116

Form: Participant Creation

Data signed: (b) (4) 19 Feb 2021 19:46:07

Generated On: 09 Jun 2021 17:41:32

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[Participant ID](#)

US3462116

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

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US3462116

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 01:25:10

Generated On: 09 Jun 2021 17:41:32

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

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 01:25:10

Generated On: 09 Jun 2021 17:41:32

Date of Birth (MMM yyyy)	(b) (6) 1977
Age	43
Age Units	YEARS
Age (Derived)	43
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 01:25:10

Generated On: 09 Jun 2021 17:41:32

Date of Informed Consent ( <i>dd MMM yyyy</i> )	11 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input checked="" type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 01:25:10

Generated On: 09 Jun 2021 17:41:32

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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 01:25:10

Generated On: 09 Jun 2021 17:41:32

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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 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:41:32

Condition	TONSILLITIS
Start date (dd MMM yyyy)	UN UNK 1981
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 1981
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1981
Start Year (derived)	1981
Stop Month and Year (derived)	JAN 1981
Stop Year (derived)	1981



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:41:32

Condition	RESTLESS LEG SYNDROME
Start date (dd MMM yyyy)	UN UNK 2006
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 2006
Start Year (derived)	2006
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:41:32

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

US3462116

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:41:32

Condition	HODGKINS LYMPHOMA
Start date (dd MMM yyyy)	UN UNK 2003
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 2004
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2003
Start Year (derived)	2003
Stop Month and Year (derived)	JAN 2004
Stop Year (derived)	2004

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:41:32

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN UNK 2004
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 2004
Start Year (derived)	2004
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:41:32

Condition	RIGHT ANKLE ARTHRITIS
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 2006
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1997
Start Year (derived)	1997
Stop Month and Year (derived)	JAN 2006
Stop Year (derived)	2006

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:41:32

Condition	RUPTURED L5
Start date (dd MMM yyyy)	UN UNK 1991
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 1991
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1991
Start Year (derived)	1991
Stop Month and Year (derived)	JAN 1991
Stop Year (derived)	1991

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:41:32

Condition	RUPTURED L6
Start date (dd MMM yyyy)	UN UNK 2006
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 2006
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2006
Start Year (derived)	2006
Stop Month and Year (derived)	JAN 2006
Stop Year (derived)	2006

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:41:32

Condition	TUBAL LIGATION
Start date (dd MMM yyyy)	UN NOV 2005
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 NOV 2005
Stop date completely unknown	False
Start Month and Year (derived)	NOV 2005
Start Year (derived)	2005
Stop Month and Year (derived)	NOV 2005
Stop Year (derived)	2005



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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:41:32

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

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:41:32

Condition	LUMBAR DISCECTOMY
Start date (dd MMM yyyy)	UN UNK 1991
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 1991
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1991
Start Year (derived)	1991
Stop Month and Year (derived)	JAN 1991
Stop Year (derived)	1991

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:41:32

Condition	TONSILLECTOMY
Start date (dd MMM yyyy)	UN UNK 1981
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 1981
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1981
Start Year (derived)	1981
Stop Month and Year (derived)	JAN 1981
Stop Year (derived)	1981

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:41:32

Condition	LUMBAR DISECTOMY
Start date (dd MMM yyyy)	UN UNK 2006
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 2006
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2006
Start Year (derived)	2006
Stop Month and Year (derived)	JAN 2006
Stop Year (derived)	2006

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:41:32

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

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:41:32

Condition	EXERTIONAL BRONCHOSPASM
Start date (dd MMM yyyy)	UN UNK 2004
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 2004
Start Year (derived)	2004
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:41:32

Condition	METHAMPHETAMINE ABUSE 1993-2003
Start date (dd MMM yyyy)	UN UNK 1993
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 2003
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1993
Start Year (derived)	1993
Stop Month and Year (derived)	JAN 2003
Stop Year (derived)	2003

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:41:32

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



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Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:41:32

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

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Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:41:32

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

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Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:41:32

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 01:25:10

Generated On: 09 Jun 2021 17:41:32

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	11 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	10:58 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 10:58
Height ( <i>xxx.x</i> )	173 cm
Weight ( <i>xxx.x</i> )	108 kg
BMI ( <i>xxx.x</i> )	36.08540 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 01:25:10

Generated On: 09 Jun 2021 17:41:32

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 13 Feb 2021 01:25:10

Generated On: 09 Jun 2021 17:41:32

Date of assessment (dd MMM yyyy) 11 AUG 2020

Is the participant of childbearing potential? Yes ☐  
No ☒

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

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

If Surgically sterile, date of surgery (dd MMM yyyy) UN NOV 2005

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 01:25:10

Generated On: 09 Jun 2021 17:41:32

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☒

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**Specify**

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

**No Risk Identified** True

**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 01:25:10

Generated On: 09 Jun 2021 17:41:32

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



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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 01:25:10

Generated On: 09 Jun 2021 17:41:32

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 01:25:10

Generated On: 09 Jun 2021 17:41:32

What was the date of randomization? (dd MMM yyyy) 11 AUG 2020

What was the participant's randomization number? 103130

In what Cohort was the participant enrolled?   
 >=18 and <65 years and not at risk ☒   
 >=18 and <65 years and at risk ☐   
 >=65 years ☐

If participant is considered at risk, please check all that apply (If any are checked as Yes, please ensure the actual condition is recorded on the Medical History form)

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma) Yes ☐ No ☒

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension) Yes ☐ No ☒

Severe obesity (body mass index > or = 40kg/m2) Yes ☐ No ☒

Diabetes (Type I, Type 2, or gestational) Yes ☐ No ☒

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 01:25:10

Generated On: 09 Jun 2021 17:41:32

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 01:25:10

Generated On: 09 Jun 2021 17:41:32

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)	11 AUG 2020
Time of assessment (00:00-23:59)	10:58 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 10:58
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 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 01:25:10

Generated On: 09 Jun 2021 17:41:32

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)	11 AUG 2020
Time of assessment (00:00-23:59)	12:53 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 12:53
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	95 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	152 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 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 01:25:10

Generated On: 09 Jun 2021 17:41:32

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 01:25:10

Generated On: 09 Jun 2021 17:41:32

Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐  
Physician withheld dose due to Adverse Event ☐  
Death ☐  
Lost To Follow-Up ☐  
Physician Decision ☐  
Pregnancy ☐  
Protocol Deviation ☐  
Study Terminated by Sponsor ☐  
Withdrawal of Consent by Participant ☐  
Confirmed COVID-19 ☐  
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 12:22 (24 HR)

Treatment Date and Time (derived) 11 AUG 2020 12:22

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 01:25:10

Generated On: 09 Jun 2021 17:41:32

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

11 AUG 2020

Collection time (00:00-23:59)

11:50 (24 HR)

Collection date and time (derived)

11 AUG 2020 11:50



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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 01:25:10

Generated On: 09 Jun 2021 17:41:32

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

US3462116

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:25:10

Generated On: 09 Jun 2021 17:41:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:41:32

**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

93.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 AUG 2020 12:55

PC Open Date & Time

11 AUG 2020 12:42

PC Close Date & Time

11 AUG 2020 15:12

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.4 °F

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

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

PC Time Stamp	11 AUG 2020 16:10
PC Open Date & Time	11 AUG 2020 16:07
PC Close Date & Time	12 AUG 2020 11:59

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 AUG 2020 12:41

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:41:32

**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

98.0 °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

13 AUG 2020 12:08

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

14 AUG 2020 14:59

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:41:32

**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

15 AUG 2020 12:00

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59



US3462116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 AUG 2020 14:51

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:41:32

**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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 AUG 2020 12:18

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:41:32

**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

11 AUG 2020 12:56

PC Open Date & Time

11 AUG 2020 12:42

PC Close Date & Time

11 AUG 2020 15:12

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:41:32

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

4

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

11 AUG 2020 16:12

PC Open Date & Time

11 AUG 2020 16:07

PC Close Date & Time

12 AUG 2020 11:59

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:41:32

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

4

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

12 AUG 2020 12:41

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:41:32

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

3

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

13 AUG 2020 12:08

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

14 AUG 2020 15:00

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

15 AUG 2020 12:01

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59



US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

16 AUG 2020 14:51

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

17 AUG 2020 12:18

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:41:32

**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 ☐

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:41:32

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

No ☒

Yes ☐

PC Time stamp	11 AUG 2020 12:57
PC Open Date & Time	11 AUG 2020 12:42
PC Close Date & Time	11 AUG 2020 15:12

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:41:32

**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 ☐

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:41:32

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

No ☒

Yes ☐

PC Time stamp	11 AUG 2020 16:12
PC Open Date & Time	11 AUG 2020 16:07
PC Close Date & Time	12 AUG 2020 11:59

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:41:32

**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)

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:41:32

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 12:41
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59



US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:41:32

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 ☒

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:41:32

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 12:09
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:41:32

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)

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:41:32

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

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:41:32

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:41:32

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

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:41:32

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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EAB) (1725)

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:41:32

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 14:51
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59



US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:41:32

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 ☒

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:41:32

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

US3462116

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:25:10

Generated On: 09 Jun 2021 17:41:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3462116

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:25:10

Generated On: 09 Jun 2021 17:41:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462116

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:25:10

Generated On: 09 Jun 2021 17:41:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3462116

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:25:10

Generated On: 09 Jun 2021 17:41:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462116

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:25:10

Generated On: 09 Jun 2021 17:41:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3462116

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:25:10

Generated On: 09 Jun 2021 17:41:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3462116

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 01:25:10

Generated On: 09 Jun 2021 17:41:32

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3462116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 01:25:10

Generated On: 09 Jun 2021 17:41:32

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 SEP 2020
Time of assessment (00:00-23:59)	13:26 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 13:26
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3462116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 01:25:10

Generated On: 09 Jun 2021 17:41:32

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 SEP 2020
Time of assessment (00:00-23:59)	14:21 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 14:21
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	88 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3462116

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 01:25:10

Generated On: 09 Jun 2021 17:41:32

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 SEP 2020

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

US3462116

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 01:25:10

Generated On: 09 Jun 2021 17:41:32

Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐  
Physician withheld dose due to Adverse Event ☐  
Death ☐  
Lost To Follow-Up ☐  
Physician Decision ☐  
Pregnancy ☐  
Protocol Deviation ☐  
Study Terminated by Sponsor ☐  
Withdrawal of Consent by Participant ☐  
Confirmed COVID-19 ☐  
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 14 SEP 2020

What was the treatment time? (00:00-23:59) 13:50 (24 HR)

Treatment Date and Time (derived) 14 SEP 2020 13:50

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

What was the frequency of the study treatment dosing? ONCE

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

US3462116

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 01:25:10

Generated On: 09 Jun 2021 17:41:32

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 SEP 2020
Collection time (00:00-23:59)	13:41 (24 HR)
Collection date and time (derived)	14 SEP 2020 13:41

US3462116

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 01:25:10

Generated On: 09 Jun 2021 17:41:32

Collection date (dd MMM yyyy)			14 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:43	14 SEP 2020 13:43
Nasopharyngeal Swab 2	No		

US3462116

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:25:10

Generated On: 09 Jun 2021 17:41:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3462116

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:41:32

**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 14 SEP 2020 14:20

PC Open Date & Time 14 SEP 2020 14:10

PC Close Date & Time 14 SEP 2020 16:40

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:41:32

**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 97.0 °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	14 SEP 2020 17:40
PC Open Date & Time	14 SEP 2020 17:35
PC Close Date & Time	15 SEP 2020 11:59

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:41:32

**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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:41:32

**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

97.5 °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

16 SEP 2020 17:37

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

17 SEP 2020 12:18

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 SEP 2020 14:48

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:41:32

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**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 SEP 2020 12:02

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °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

20 SEP 2020 17:14

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59



US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:41:32

**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

14 SEP 2020 14:20

PC Open Date & Time

14 SEP 2020 14:10

PC Close Date & Time

14 SEP 2020 16:40

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

14 SEP 2020 17:40

PC Open Date & Time

14 SEP 2020 17:35

PC Close Date & Time

15 SEP 2020 11:59

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:41:32

**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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

16 SEP 2020 17:38

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

17 SEP 2020 12:18

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

18 SEP 2020 14:48

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

19 SEP 2020 12:02

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

20 SEP 2020 17:14

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59



US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:41:32

**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 ☐

US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:41:32

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

No ☒

Yes ☐

PC Time stamp	14 SEP 2020 14:20
PC Open Date & Time	14 SEP 2020 14:10
PC Close Date & Time	14 SEP 2020 16:40

US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:41:32

**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 ☐

US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:41:32

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

No ☒

Yes ☐

PC Time stamp	14 SEP 2020 17:40
PC Open Date & Time	14 SEP 2020 17:35
PC Close Date & Time	15 SEP 2020 11:59

US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:41:32

**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 ☐

US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:41:32

Yes ☐

PC Time stamp

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:41:32

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

110 of 2479

EAB) (1725)

US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:41:32

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 17:38
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59



US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:41:32

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 ☒

PRODUCTION RELEASE (v12.003

112 of 2479

EAB) (1725)

US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:41:32

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

US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:41:32

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

114 of 2479

EAB) (1725)

US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:41:32

Yes <input type="checkbox"/>	
PC Time stamp	18 SEP 2020 14:49
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:41:32

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

116 of 2479

EAB) (1725)

US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:41:32

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 12:02
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:41:32

**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 ☒

US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:41:32

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 17:14
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59



US3462116

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:25:10

Generated On: 09 Jun 2021 17:41:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3462116

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:25:10

Generated On: 09 Jun 2021 17:41:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462116

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:25:10

Generated On: 09 Jun 2021 17:41:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3462116

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:25:10

Generated On: 09 Jun 2021 17:41:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462116

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:25:10

Generated On: 09 Jun 2021 17:41:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3462116

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:25:10

Generated On: 09 Jun 2021 17:41:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462116

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 01:25:10

Generated On: 09 Jun 2021 17:41:32

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3462116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 01:25:10

Generated On: 09 Jun 2021 17:41:32

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) \_\_\_\_\_



US3462116

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 01:25:10

Generated On: 09 Jun 2021 17:41:32

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.*

US3462116

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 01:25:10

Generated On: 09 Jun 2021 17:41:32

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

13 OCT 2020

Collection time (00:00-23:59)

15:50 (24 HR)

Collection date and time (derived)

13 OCT 2020 15:50

US3462116

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:25:10

Generated On: 09 Jun 2021 17:41:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

DAY 64

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 OCT 2020 14:12:18

Patient Cloud Open Date & Time

11 OCT 2020 00:01

Patient Cloud Close Date & Time

15 OCT 2020 23:59

US3462116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

**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

19 OCT 2020 14:03:56

Patient Cloud Open Date & Time

18 OCT 2020 00:01

Patient Cloud Close Date & Time

22 OCT 2020 23:59

US3462116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

**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

25 OCT 2020 12:48:47

Patient Cloud Open Date & Time

25 OCT 2020 00:01

Patient Cloud Close Date & Time

29 OCT 2020 23:59

US3462116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

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 <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	08 NOV 2020 23:04:55
Patient Cloud Open Date & Time	08 NOV 2020 00:01
Patient Cloud Close Date & Time	12 NOV 2020 23:59

US3462116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

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	17 NOV 2020 13:34:28
Patient Cloud Open Date & Time	15 NOV 2020 00:01
Patient Cloud Close Date & Time	19 NOV 2020 23:59



US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 NOV 2020 21:27:12

Patient Cloud Open Date & Time

19 NOV 2020 00:01

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

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	26 NOV 2020 10:31:33
Patient Cloud Open Date & Time	26 NOV 2020 00:01
Patient Cloud Close Date & Time	30 NOV 2020 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

**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

03 DEC 2020 03:50:25

Patient Cloud Open Date & Time

03 DEC 2020 00:01

Patient Cloud Close Date & Time

07 DEC 2020 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

**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

10 DEC 2020 08:59:03

Patient Cloud Open Date & Time

10 DEC 2020 00:01

Patient Cloud Close Date & Time

14 DEC 2020 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

**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

17 DEC 2020 10:14:38

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

**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

24 DEC 2020 10:32:18

Patient Cloud Open Date & Time

24 DEC 2020 00:01

Patient Cloud Close Date & Time

28 DEC 2020 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

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 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"/>

**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

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

[Patient Cloud Close Date & Time](#)

04 JAN 2021 23:59



US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

**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

11 JAN 2021 09:06:06

Patient Cloud Open Date & Time

07 JAN 2021 00:01

Patient Cloud Close Date & Time

11 JAN 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

**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

16 JAN 2021 13:20:00

Patient Cloud Open Date & Time

14 JAN 2021 00:01

Patient Cloud Close Date & Time

18 JAN 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

DAY 166

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

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

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

**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

**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

29 JAN 2021 11:03:18

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 FEB 2021 16:03:31

Patient Cloud Open Date & Time

04 FEB 2021 00:01

Patient Cloud Close Date & Time

08 FEB 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

<b>TIMEPOINT</b>	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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 FEB 2021 01:04:04
Patient Cloud Open Date & Time	11 FEB 2021 00:01
Patient Cloud Close Date & Time	15 FEB 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 FEB 2021 11:27:49

Patient Cloud Open Date & Time

18 FEB 2021 00:01

Patient Cloud Close Date & Time

22 FEB 2021 23:59



US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 FEB 2021 21:44:54

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

**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

04 MAR 2021 14:53:32

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

**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

11 MAR 2021 09:55:06

Patient Cloud Open Date & Time

11 MAR 2021 00:01

Patient Cloud Close Date & Time

15 MAR 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 MAR 2021 00:01:38

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

**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

25 MAR 2021 13:39:07

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

<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	01 APR 2021 01:12:21
Patient Cloud Open Date & Time	01 APR 2021 00:01
Patient Cloud Close Date & Time	05 APR 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	08 APR 2021 09:18:23
Patient Cloud Open Date & Time	08 APR 2021 00:01
Patient Cloud Close Date & Time	12 APR 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

**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

15 APR 2021 08:45:50

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59



US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

**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

24 APR 2021 14:45:51

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

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

**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

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

**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

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

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[Patient Cloud Open Date & Time](#)

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06 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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10 MAY 2021 23:59

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US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

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

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

**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

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

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[Patient Cloud Open Date & Time](#)

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13 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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17 MAY 2021 23:59

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US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

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



**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

**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 ☐

**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

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

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

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

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[Patient Cloud Open Date & Time](#)

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03 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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07 JUN 2021 23:59

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US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

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

**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

**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 ☐



**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

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"/>

**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

DAY 327

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

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

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

**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 ☐

**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

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



**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

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

15 JUL 2021 00:01

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19 JUL 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

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

**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2021 00:01

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26 JUL 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

**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 ☐

**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

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02 AUG 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

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

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05 AUG 2021 00:01

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09 AUG 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

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 <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"/>



**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

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

12 AUG 2021 00:01

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16 AUG 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

DAY 376

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

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

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

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

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

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

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

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

**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

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

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[Patient Cloud Open Date & Time](#)

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19 AUG 2021 00:01

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23 AUG 2021 23:59

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US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

**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 ☐

**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

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

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26 AUG 2021 00:01

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30 AUG 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

**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°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 ☐

**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 SEP 2021 00:01

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06 SEP 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

**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 ☐



**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

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

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09 SEP 2021 00:01

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13 SEP 2021 23:59

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US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

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"/>

**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

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

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16 SEP 2021 00:01

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20 SEP 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

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

**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

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

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23 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

DAY 418

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

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

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

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

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

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

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

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

**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

DAY 425

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

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

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

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

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

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

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

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



**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

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

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

**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

18 OCT 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 OCT 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

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"/>

**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

DAY 453

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

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

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

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

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

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

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

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



**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

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

**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

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"/>

**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

DAY 481

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

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

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

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

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

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

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

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



**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

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

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[Patient Cloud Open Date & Time](#)

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02 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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06 DEC 2021 23:59

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US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

DAY 495

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

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

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

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

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

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

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

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

**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

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

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

**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 ☐

**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

27 DEC 2021 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

**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 ☐



**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

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10 JAN 2022 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

**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 ☐

**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

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

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13 JAN 2022 00:01

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17 JAN 2022 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

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

**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

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

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24 JAN 2022 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

**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 ☐



**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JAN 2022 00:01

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31 JAN 2022 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

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

**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 FEB 2022 00:01

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07 FEB 2022 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

**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 ☐

**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

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

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[Patient Cloud Open Date & Time](#)

10 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

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US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

**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 ☐

**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

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

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[Patient Cloud Open Date & Time](#)

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17 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 FEB 2022 23:59

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US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

**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 ☐



**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 FEB 2022 00:01

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28 FEB 2022 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

**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 ☐

**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 MAR 2022 00:01

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07 MAR 2022 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

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

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10 MAR 2022 00:01

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14 MAR 2022 23:59

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US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

**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 ☐

**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

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

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17 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

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US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

**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 ☐



**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

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

**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

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

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[Patient Cloud Close Date & Time](#)

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04 APR 2022 23:59

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US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

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"/>

**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

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"/>

**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

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"/>



**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

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

21 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2022 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

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"/>

**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

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

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

DAY 642

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

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

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

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

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

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

**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

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

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[Patient Cloud Open Date & Time](#)

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12 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 MAY 2022 23:59

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US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

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"/>



**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

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

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30 MAY 2022 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

**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°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 ☐

**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

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06 JUN 2022 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

DAY 670

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

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

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

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

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

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

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 ☐

**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

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

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09 JUN 2022 00:01

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13 JUN 2022 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

**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 ☐



**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

DAY 684

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

DAY 691

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

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

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

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

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

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

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

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

**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2022 00:01

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04 JUL 2022 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

**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 ☐

**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUL 2022 00:01

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11 JUL 2022 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JUL 2022 00:01

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18 JUL 2022 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

**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 ☐

**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

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

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[Patient Cloud Open Date & Time](#)

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21 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 JUL 2022 23:59

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US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

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"/>

**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

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"/>

**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

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

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[Patient Cloud Open Date & Time](#)

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04 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 AUG 2022 23:59

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US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

DAY 733

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

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

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

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

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

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

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

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



**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 AUG 2022 00:01

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15 AUG 2022 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

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"/>

**US3462116**

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

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**Generated On: 09 Jun 2021 17:41:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2022 00:01

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22 AUG 2022 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

DAY 747

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3462116**

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

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**Generated On: 09 Jun 2021 17:41:32**

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

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[Patient Cloud Open Date & Time](#)

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25 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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29 AUG 2022 23:59

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US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

DAY 754

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

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

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

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

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

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

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

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

**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

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

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01 SEP 2022 00:01

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05 SEP 2022 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	08 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	12 SEP 2022 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

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"/>

**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

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

15 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2022 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

**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 ☐

**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

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

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[Patient Cloud Close Date & Time](#)

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26 SEP 2022 23:59

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US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

**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 ☐

**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

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

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[Patient Cloud Open Date & Time](#)

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29 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 OCT 2022 23:59

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US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	06 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	10 OCT 2022 23:59

US3462116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

**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 ☐ Yes ☐

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

**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2022 23:59

US3462116

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:41:32

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		01 MAR 2021 15:08:12

US3462116

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:46:08

Generated On: 09 Jun 2021 17:41:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3462116

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:46:08

Generated On: 09 Jun 2021 17:41:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462116

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:46:08

Generated On: 09 Jun 2021 17:41:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3462116

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:46:08

Generated On: 09 Jun 2021 17:41:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3462116

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:46:08

Generated On: 09 Jun 2021 17:41:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

07 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3462116

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:46:08

Generated On: 09 Jun 2021 17:41:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462116

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:46:08

Generated On: 09 Jun 2021 17:41:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3462116

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:46:08

Generated On: 09 Jun 2021 17:41:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462116

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 19 Mar 2021 19:07:47

Generated On: 09 Jun 2021 17:41:32

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3462116

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 31 Mar 2021 21:37:16

Generated On: 09 Jun 2021 17:41:32

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	26 FEB 2021
Time of assessment ( <i>00:00-23:59</i> )	11:14 (24 HR)
Vital Signs Date and Time (derived)	26 FEB 2021 11:14
Temperature ( <i>xxx.x</i> )	96.9 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse ( <i>xxx</i> )	104 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	83 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3462116

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Mar 2021 19:07:30

Generated On: 09 Jun 2021 17:41:32

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.*

US3462116

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Mar 2021 19:07:30

Generated On: 09 Jun 2021 17:41:32

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

26 FEB 2021

Collection time (00:00-23:59)

12:00 (24 HR)

Collection date and time (derived)

26 FEB 2021 12:00



US3462116

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 19:07:30

Generated On: 09 Jun 2021 17:41:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462116

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 13:10:24

Generated On: 09 Jun 2021 17:41:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

06 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3462116

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 13:10:24

Generated On: 09 Jun 2021 17:41:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3462116**

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

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:41:32**

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*

**US3462116**

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

**Form: Continuing**

**Generated On: 09 Jun 2021 17:41:32**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3462116

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:41:32

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"/>

**US3462116**

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

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

**Generated On: 09 Jun 2021 17:41:32**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

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US3462116

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

Form: Visit Date

Data signed: (b) (4) 19 Mar 2021 19:07:30

Generated On: 09 Jun 2021 17:41:32

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

Visit date (dd MMM yyyy)	29 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3462116

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

Form: Unblinding

Data signed: (b) (4) 19 Mar 2021 19:07:30

Generated On: 09 Jun 2021 17:41:32

Date of updated informed consent ( <i>dd MMM yyyy</i> )	29 JAN 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> )	29 JAN 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

US3462116

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 22 Apr 2021 22:33:05

Generated On: 09 Jun 2021 17:41:32

Height	172 cm
Weight	105.7 kg
BMI (xxx.x)	35.72877

US3462116

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Apr 2021 22:33:05

Generated On: 09 Jun 2021 17:41:32

Height	172 cm
Weight	105.7 kg
BMI (xxx.x)	35.72877
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	29 JAN 2021
Time of assessment (00:00-23:59)	11:55 (24 HR)
Vital Signs Date and Time (derived)	29 JAN 2021 11:55
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	85 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	180 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3462116

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Apr 2021 22:33:05

Generated On: 09 Jun 2021 17:41:32

Height	172 cm
Weight	105.7 kg
BMI (xxx.x)	35.72877
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)	29 JAN 2021
Time of assessment (00:00-23:59)	13:20 (24 HR)
Vital Signs Date and Time (derived)	29 JAN 2021 13:20
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	87 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3462116

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

Form: Physical Examination

Data signed: (b) (4) 19 Mar 2021 19:07:30

Generated On: 09 Jun 2021 17:41:32

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.*

US3462116

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

Form: Exposure

Data signed: (b) (4) 19 Mar 2021 19:07:30

Generated On: 09 Jun 2021 17:41:32

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) 29 JAN 2021

What was the treatment time? (00:00-23:59) 12:50 (24 HR)

Treatment Date and Time (derived) 29 JAN 2021 12:50

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

What was the frequency of the study treatment dosing? ONCE

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

US3462116

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Mar 2021 19:07:30

Generated On: 09 Jun 2021 17:41:32

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

29 JAN 2021

Collection time (00:00-23:59)

11:48 (24 HR)

Collection date and time (derived)

29 JAN 2021 11:48

US3462116

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 19 Mar 2021 19:07:30

Generated On: 09 Jun 2021 17:41:32

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

Collection date (dd MMM yyyy)	29 JAN 2021
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Collection time (00:00 - 23:59)	11:37
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Collection Date and Time (derived)	29 JAN 2021 11:37
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US3462116

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

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 19:07:30

Generated On: 09 Jun 2021 17:41:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462116

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 19:07:30

Generated On: 09 Jun 2021 17:41:32

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

US3462116

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 19:07:30

Generated On: 09 Jun 2021 17:41:32

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

US3462116

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Mar 2021 19:07:30

Generated On: 09 Jun 2021 17:41:32

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3462116

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Apr 2021 21:21:44

Generated On: 09 Jun 2021 17:41:32

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 FEB 2021
Time of assessment (00:00-23:59)	11:14 (24 HR)
Vital Signs Date and Time (derived)	26 FEB 2021 11:14
Temperature (xxx.x)	96.9 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	104 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3462116

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Apr 2021 21:21:44

Generated On: 09 Jun 2021 17:41:32

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 FEB 2021
Time of assessment (00:00-23:59)	12:24 (24 HR)
Vital Signs Date and Time (derived)	26 FEB 2021 12:24
Temperature (xxx.x)	97.1 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	100 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3462116

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Mar 2021 19:07:30

Generated On: 09 Jun 2021 17:41:32

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.*

US3462116

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 19 Mar 2021 19:07:30

Generated On: 09 Jun 2021 17:41:32

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 FEB 2021

What was the treatment time? (00:00-23:59) 11:53 (24 HR)

Treatment Date and Time (derived) 26 FEB 2021 11:53

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



US3462116

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 19:07:30

Generated On: 09 Jun 2021 17:41:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462116

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 31 Mar 2021 00:04:55

Generated On: 09 Jun 2021 17:41:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3462116

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 31 Mar 2021 00:04:55

Generated On: 09 Jun 2021 17:41:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462116

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 13:10:24

Generated On: 09 Jun 2021 17:41:32

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 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

US3462116

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Apr 2021 13:10:24

Generated On: 09 Jun 2021 17:41:32

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) \_\_\_\_\_

US3462116

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 13:10:24

Generated On: 09 Jun 2021 17:41:32

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.*

US3462116

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Apr 2021 13:10:24

Generated On: 09 Jun 2021 17:41:32

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

08 APR 2021

Collection time (00:00-23:59)

14:04 (24 HR)

Collection date and time (derived)

08 APR 2021 14:04

US3462116

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Feb 2021 19:46:07

Generated On: 09 Jun 2021 17:41:32

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---



US3462116

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Mar 2021 19:07:29

Generated On: 09 Jun 2021 17:41:32

AEID	USA-US093-2020-MRNA-1273-P30 1000003
Adverse event	CONGESTIVE HEART FAILURE
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)	03 SEP 2020
Start time (00:00-23:59)	08:00 (24 HR)
AE start date and time (derived)	03 SEP 2020 08:00
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	09 SEP 2020
End time (00:00-23:59)	17:00 (24 HR)
AE End Date and Time (derived)	09 SEP 2020 17:00
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)	05 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	09 SEP 2020
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 (1)

Data signed: (b) (4) 19 Mar 2021 19:07:29

Generated On: 09 Jun 2021 17:41:32

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product 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	

US3462116

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Mar 2021 19:07:29

Generated On: 09 Jun 2021 17:41:32

---

PATIENT IS 43 YEAR OLD  
WOMAN WITH SOCIAL RISK  
FOR COVID-19. SHE  
CONSENTED AND  
RANDOMIZED ON 11AUG2020  
AND TOLERATED DOSE 1  
UNEVENTFULLY. SHE  
DEVELOPED NEW ONSET  
INCREASED DYSPNEA AND  
FLUID RETENTION THAT  
BECAME CLINICALLY  
BOTHERSOME ON 08:00 ON  
03SEP2020. SHE WENT TO  
ROGUE REGIONAL MEDICAL  
CENTER IN MEDFORD, OR AT  
APPROXIMATELY 09:00 ON  
04SEP2020, AND WAS  
ADMITTED FOR NEW ONSET  
CONGESTIVE HEART FAILURE  
(CHF). CHF WAS CONFIRMED  
ON CHEST X-RAY AND  
ECHOCARDIOGRAM, AND  
OTHER HEART DISEASE WAS  
RULED WITH ANGIOGRAM AND  
CHEST CT. PATIENT WAS  
DIURESED WITH FUROSEMIDE  
AND RECOVERED FULLY. SHE  
WAS DISCHARGED TO HOME  
ON 09SEP2020 AT ABOUT 17:00  
ON NEW ORAL DIURETIC  
MEDICATIONS TO PREVENT  
CHF. ALL HISTORY FROM  
PHONE CALL TO PATIENT ON  
09SEP2020 AT 18:30. WE ARE  
REPORTING THIS SAE

US3462116

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Mar 2021 19:07:29

Generated On: 09 Jun 2021 17:41:32

---

TODAY.  
SAE REPORT UPDATED  
05NOV2020 BASED ON  
HOSPITAL DISCHARGE  
SUMMARY. DC SUMMARY  
CONFIRMS ADMIT DATE WAS  
05SEP2020 AND DC DATE  
09SEP2020. PRIMARY  
DIAGNOSIS WAS ACUTE CHF  
THAT IMPROVED AFTER 2  
LITERS DIURESIS WITH  
FUROSEMIDE. ECHO  
CONFIRMED LOW LVEF OF 30%  
CONFIRMING SYSTOLIC CHF.

SUBJECT ALSO HAD A LEFT  
HEART CATERITERATION  
TEST PERFORMED WHICH  
SHOWED NORMAL CORONARY  
ARTERIES. FAMILY HISTORY  
WAS POSITIVE FOR (b) (6)  
AND (b) (6) BOTH  
DYING IN 40S WITH POSSIBLE  
FAMILIAL CARDIOMYOPATHY  
AND CHF. SUBJECT ALSO HAD  
REMOTE HISTORY OF  
METHAMPHETAMINE ABUSE  
1993-2003 THAT MAY HAVE  
CONTRIBUTED TO  
CARDIOMYOPATHY.  
THEREFORE, PATIENT SEEMS  
TO HAVE A PREVIOUSLY  
UNDIAGNOSED FAMILIAL  
CARDIOMYOPATHY WHICH  
MAY BE DO TO A) HISTORY OF

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Mar 2021 19:07:29

Generated On: 09 Jun 2021 17:41:32

---

CHF IN (b) (6) AND (b) (6) , B)  
WEIGHT LIFTING AND  
METHAMPHETAMINE ABUSE  
AS TEENAGER AND YOUNG  
ADULT, AND C) PATIENT ALSO  
SEEMS TO HAVE BORDERLINE  
DIABETES TYPE II THAT MAY  
CONTRIBUTE TO  
CARDIOMYOPATHY. SHE WAS  
DISCHARGED TO HOME ON  
NEW MEDS FOR  
CARDIOMYOPATHY  
INCLUDING 5 MEDICATIONS,  
AND WITH FOLLOW-UP WITH  
CARDIOLOGIST PLANNED IN  
2-3 MONTHS. SAE IS UPDATED  
TODAY WITH THIS  
INFORMATION FROM  
HOSPITAL RECORDS.

---

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

---

US3462116

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 19 Mar 2021 19:07:29

Generated On: 09 Jun 2021 17:41:32

AEID	
Adverse event	FAMILIAL CARDIOMYOPATHY
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)	05 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 19 Mar 2021 19:07:29

Generated On: 09 Jun 2021 17:41:32

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

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Feb 2021 19:46:08

Generated On: 09 Jun 2021 17:41:32

---

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

Yes ☒

No ☐

---

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

---



US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:41:32

Name of Medication SYNTHROID

Prophylaxis Yes ☐  
No ☒

Indication HYPOTHYROIDISM

Dose per administration 112

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:41:32

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2005	
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"/>

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:41:32

Name of Medication	REQUIP
Prophylaxis	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

Indication	RESTLESS LEG SYNDROME
------------	-----------------------

Dose per administration	2.5
-------------------------	-----

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 checked="" type="radio"/>
	three times daily <input type="radio"/>
	four times daily <input type="radio"/>
	every other day <input type="radio"/>
	every week <input type="radio"/>
	every month <input type="radio"/>
	as needed <input type="radio"/>
	once <input type="radio"/>
	unknown <input type="radio"/>
	other <input type="radio"/>

If frequency is Other, specify

Route of administration	Oral <input checked="" type="radio"/>
	Topical <input type="radio"/>
	Subcutaneous <input type="radio"/>
	Transdermal <input type="radio"/>
	Intraocular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:41:32

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2007	
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"/>

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:41:32

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication OCCASIONAL HEADACHE

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 ☐  
Intraocular ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:41:32

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2000	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:41:32

Name of Medication ASPIRIN

Prophylaxis Yes ☒  
No ☐

Indication CARDIAC PROPHYLAXIS

Dose per administration 81

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) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:41:32

	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)		09 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:41:32

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐  
No ☒

Indication FAMILIAL CARDIOMYOPATHY/  
CONGESTIVE HEART FAILURE

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 (5)

Data signed: (b) (4) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:41:32

	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 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:41:32

Name of Medication CARVEDILOL

Prophylaxis Yes ☐  
No ☒

Indication FAMILIAL CARDIOMYOPATHY/  
CONGESTIVE HEART FAILURE

Dose per administration 3.125

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:41:32

	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 type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		09 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 13 Apr 2021 00:44:54

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Name of Medication FUROSEMIDE

Prophylaxis Yes ☐  
No ☒

Indication FAMILIAL CARDIOMYOPATHY/  
CONGESTIVE HEART FAILURE

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:41:32

	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)		10 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 13 Apr 2021 00:44:54

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Name of Medication LISINOPRIL

Prophylaxis Yes ☐  
No ☒

Indication FAMILIAL  
CARDIOMYOPATHY/CONGESTI  
VE HEART FAILURE

Dose per administration 2.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:41:32

	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)		10 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 13 Apr 2021 00:44:54

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Name of Medication SPIRONOLACTONE

Prophylaxis Yes ☐  
No ☒

Indication FAMILIAL CARDIOMYOPATHY/  
CONGESTIVE HEART FAILURE

Dose per administration 6.25

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 (9)

Data signed: (b) (4) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:41:32

	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)		10 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:41:32

Name of Medication LANTUS

Prophylaxis Yes ☐  
No ☒

Indication TYPE II DIABETES

Dose per administration 22

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

If dose unit is Other, specify UNITS

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:41:32

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 13 Apr 2021 00:44:54

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Name of Medication INSULIN LISPRO

Prophylaxis Yes ☐  
No ☒

Indication TYPE II DIABETES

Dose per administration 2

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

If dose unit is Other, specify UNITS

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 (11)

Data signed: (b) (4) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:41:32

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:41:32

Name of Medication ALBUTEROL

Prophylaxis Yes ☐  
No ☒

Indication EXERTIONAL BRONCHOSPASM

Dose per administration 180

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 (12)

Data signed: (b) (4) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:41:32

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 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 (13)

Data signed: (b) (4) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:41:32

Name of Medication LOVENOX

Prophylaxis Yes ☒  
No ☐

Indication CARDIAC PROPHYLAXIS

Dose per administration 30

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) 13 Apr 2021 00:44:54

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	15 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		07 APR 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 (14)

Data signed: (b) (4) 13 Apr 2021 00:44:54

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Name of Medication GENERAL ANESTHESIA

Prophylaxis Yes ☐  
No ☒

Indication L BELOW THE KNEE  
AMPUTATION

Dose per administration UNK

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

If dose unit is Other, specify UNKNOWN

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 (14)

Data signed: (b) (4) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:41:32

	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)	15 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		15 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"/>

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:41:32

Name of Medication GENERAL ANESTHESIA

Prophylaxis Yes ☐  
No ☒

Indication R BELOW THE KNEE  
AMPUTATION

Dose per administration UNK

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

If dose unit is Other, specify UNKNOWN

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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US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:41:32

	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)	29 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		29 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"/>

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:41:32

Name of Medication NORCO

Prophylaxis Yes ☐  
No ☒

Indication BILATERAL CHRONIC FOOT  
PAIN

Dose per administration 300/5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:41:32

	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)	01 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	14 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>



US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:41:32

Name of Medication NORCO

Prophylaxis Yes ☐  
No ☒

Indication POST-SURGICAL PAIN

Dose per administration 300/5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:41:32

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

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:41:32

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

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) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:41:32

	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 type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	01 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	14 MAR 2021	
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"/>

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:41:32

Name of Medication ROBAXIN

Prophylaxis Yes ☐  
No ☒

Indication POST-SURGICAL PAIN

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:41:32

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

US3462116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 19 Feb 2021 19:46:08

Generated On: 09 Jun 2021 17:41:32

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3462116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 13 Apr 2021 00:44:54

Generated On: 09 Jun 2021 17:41:32

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
05 SEP 2020	ECHOCARDIOGRAM	Adverse Event	
05 SEP 2020	CAT SCAN	Adverse Event	
04 SEP 2020	CHEST X-RAY	Adverse Event	
08 SEP 2020	ANGIOGRAM	Adverse Event	
15 MAR 2021	L BELOW THE KNEE AMPUTATION	Medical History	
29 MAR 2021	R BELOW THE KNEE AMPUTATION	Medical History	



US3462116

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:41:32

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

US3462116

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:41:32

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 ☐

US3462116

Folder: SAE USA-US093-2020-MRNA-1273-P301000003

Form: Safety Report Form

Data signed: (b) (4) 19 Mar 2021 19:07:30

Generated On: 09 Jun 2021 17:41:32

SAEID	USA-US093-2020-MRNA-1273-P301000003
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	EDWARD
Investigator's Last Name	KERWIN
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3462116

Folder: SAE USA-US093-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Data signed: (b) (4) 19 Mar 2021 19:07:30

Generated On: 09 Jun 2021 17:41:32

SAEID	USA-US093-2020-MRNA-1273-P301000003
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	EDWARD
Investigator's Last Name	KERWIN
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	12/SEP/2020 11:31
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

US3462116

Folder: SAE USA-US093-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Data signed: (b) (4) 19 Mar 2021 19:07:30

Generated On: 09 Jun 2021 17:41:32

SAEID	USA-US093-2020-MRNA-1273-P301000003
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	EDWARD
Investigator's Last Name	KERWIN
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	06/NOV/2020 13:48
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

US3462116

Folder: SAE USA-US093-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Data signed: (b) (4) 19 Mar 2021 19:07:30

Generated On: 09 Jun 2021 17:41:32

SAEID	USA-US093-2020-MRNA-1273-P301000003
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	EDWARD
Investigator's Last Name	KERWIN
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	30/NOV/2020 18:57
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3462116

Folder: SAE USA-US093-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Data signed: (b) (4) 19 Mar 2021 19:07:30

Generated On: 09 Jun 2021 17:41:32

SAEID	USA-US093-2020-MRNA-1273-P301000003
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	EDWARD
Investigator's Last Name	KERWIN
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	16/FEB/2021 12:43
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

US3462116

Folder: SAE USA-US093-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Data signed: (b) (4) 19 Mar 2021 19:07:30

Generated On: 09 Jun 2021 17:41:32

SAEID	USA-US093-2020-MRNA-1273-P301000003
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	EDWARD
Investigator's Last Name	KERWIN
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	25/FEB/2021 12:19
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

US3462116 (Prod: Crisor, LLC)

**US3462116**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 17:41:32**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
User entered 'US3462116'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 17:14:43

US3462116

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:41:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:25:19
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	11 Aug 2020 19:30:09

US3462116

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:41:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:25:19
User entered '11 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 17:14:44

US3462116

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:41:32

[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 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:25:19
User entered 'Clinic (Clinic)'	Danuel Hamlin (b) (4)	11 Aug 2020 19:30:09

**US3462116**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:41:32**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered 'SCRN'	System	11 Aug 2020 19:30:09

US3462116

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:41:32

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:29:22
User entered (b) (6) 1977'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 17:14:45

US3462116

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:41:32

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:29:22
User entered '43'	Danuel Hamlin (b) (4)	11 Aug 2020 19:30:27



**US3462116**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:41:32**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered 'YEARS'	System	11 Aug 2020 19:30:27

**US3462116**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:41:32**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered '43'	System	11 Aug 2020 19:30:48

**US3462116**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:41:32**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:29:22
User entered 'Female (F)'	Danuel Hamlin (b) (4)	11 Aug 2020 19:30:27

US3462116

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:41:32

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:29:22
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Danuel Hamlin (b) (4)	11 Aug 2020 19:30:27

**US3462116**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:41:32**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:29:22
User entered 'I'	Danuel Hamlin (b) (4)	11 Aug 2020 19:30:27

**US3462116**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:41:32**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:29:22
User entered '0'	Danuel Hamlin (b) (4)	11 Aug 2020 19:30:27

**US3462116**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:41:32**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:29:22
User entered '0'	Danuel Hamlin (b) (4)	11 Aug 2020 19:30:27

**US3462116**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:41:32**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:29:22
User entered '0'	Danuel Hamlin (b) (4)	11 Aug 2020 19:30:27



US3462116

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:41:32

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:29:22
User entered '0'	Danuel Hamlin (b) (4)	11 Aug 2020 19:30:27

**US3462116**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:41:32**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:29:22
User entered '0'	Danuel Hamlin (b) (4)	11 Aug 2020 19:30:27

US3462116

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:41:32

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:29:22
User entered empty.	Danuel Hamlin (b) (4)	11 Aug 2020 19:30:27

**US3462116**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:41:32**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:29:22
User entered '0'	Danuel Hamlin (b) (4)	11 Aug 2020 19:30:27

**US3462116**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:41:32**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:29:22
User entered '0'	Danuel Hamlin (b) (4)	11 Aug 2020 19:30:27

US3462116

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:41:32

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:30:23
User entered '11 Aug 2020'	Danuel Hamlin (b) (4)	11 Aug 2020 19:30:48

**US3462116**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:41:32**

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered 'Aug 2020'	System	11 Aug 2020 19:30:48

**US3462116**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:41:32**

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered '2020'	System	11 Aug 2020 19:30:48



US3462116

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:41:32

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:30:23
User entered 'Amendment 2 (2)'	Danuel Hamlin (b) (4)	11 Aug 2020 19:30:48

**US3462116**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:41:32**

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:30:23
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	11 Aug 2020 19:30:48

**US3462116**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:41:32**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:30:23
User entered empty.	Danuel Hamlin (b) (4)	11 Aug 2020 19:30:48

**US3462116**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:41:32**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:30:23
User entered empty.	Danuel Hamlin (b) (4)	11 Aug 2020 19:30:48

**US3462116**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:41:32**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:30:23
User entered 'No (N)'	Danuel Hamlin (b) (4)	11 Aug 2020 19:30:48

**US3462116**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:41:32**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:30:23
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 17:14:44

**US3462116**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:41:32**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered 'I'	System	11 Aug 2020 19:30:54

US3462116

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:41:32

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:30:41
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	11 Aug 2020 19:30:54



**US3462116**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 09 Jun 2021 17:41:32**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:30:53
User entered 'Yes (Y)'		13 Aug 2020 01:53:45

US3462116

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:41:32

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Tonsillitis, LLT: Tonsillitis - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 01:56:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 01:56:12
Data point term sent to Coder	System	13 Aug 2020 01:55:09
User entered 'Tonsillitis'	(b) (4), (b) (6)	13 Aug 2020 01:54:14

**US3462116**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:41:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'un UNK 1981'	(b) (4), (b) (6)	13 Aug 2020 01:54:14

US3462116

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:41:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 01:54:14

**US3462116**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:41:32**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 01:54:14

**US3462116**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:41:32**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'un UNK 1981'	(b) (4), (b) (6)	13 Aug 2020 01:54:14

**US3462116**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:41:32**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 01:54:14

**US3462116**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:41:32**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered 'Jan 1981'	System	13 Aug 2020 01:54:14



**US3462116**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:41:32**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered '1981'	System	13 Aug 2020 01:54:14

**US3462116**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:41:32**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered 'Jan 1981'	System	13 Aug 2020 01:54:14

**US3462116**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:41:32**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered '1981'	System	13 Aug 2020 01:54:14

US3462116

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:41:32

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
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)	13 Aug 2020 01:56:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 01:56:12
Data point term sent to Coder	System	13 Aug 2020 01:55:10
User entered 'Restless Leg Syndrome'	(b) (4), (b) (6)	13 Aug 2020 01:54:32

US3462116

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:41:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'un UNK 2006'	(b) (4), (b) (6)	13 Aug 2020 01:54:32

US3462116

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:41:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 01:54:32

**US3462116**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:41:32**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 01:54:32

US3462116

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:41:32

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 01:54:32



US3462116

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:41:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 01:54:32

**US3462116**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:41:32**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered 'Jan 2006'	System	13 Aug 2020 01:54:32

**US3462116**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:41:32**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered '2006'	System	13 Aug 2020 01:54:32

**US3462116**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:41:32**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered empty.	System	13 Aug 2020 01:54:32

**US3462116**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:41:32**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered empty.	System	13 Aug 2020 01:54:32

US3462116

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:41:32

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
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)	29 Jan 2021 13:15:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	29 Jan 2021 13:15:52
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Intermittent headache - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 20:48:12
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 20:48:12
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)	13 Aug 2020 01:56:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 01:56:12
Data point term sent to Coder	System	13 Aug 2020 01:55:10
User entered 'Occasional Headaches'	(b) (4), (b) (6)	13 Aug 2020 01:54:52

US3462116

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:41:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'un UNK 2000'	(b) (4), (b) (6)	13 Aug 2020 01:54:52

**US3462116**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:41:32**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 01:54:52



**US3462116**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:41:32**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 01:54:52

**US3462116**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:41:32**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 01:54:52

**US3462116**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:41:32**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 01:54:52

**US3462116**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:41:32**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered 'Jan 2000'	System	13 Aug 2020 01:54:52

**US3462116**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:41:32**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered '2000'	System	13 Aug 2020 01:54:52

**US3462116**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:41:32**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered empty.	System	13 Aug 2020 01:54:52

**US3462116**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:41:32**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered empty.	System	13 Aug 2020 01:54:52

US3462116

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:41:32

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Lymphomas Hodgkin's disease, HLT: Hodgkin's disease NEC, PT: Hodgkin's disease, LLT: Hodgkin's lymphoma - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 01:57:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 01:57:14
Data point term sent to Coder	System	13 Aug 2020 01:56:10
User entered 'Hodgkins Lymphoma'	(b) (4), (b) (6)	13 Aug 2020 01:55:19



**US3462116**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:41:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'un UNK 2003'	(b) (4), (b) (6)	13 Aug 2020 01:55:19

US3462116

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:41:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 01:55:19

**US3462116**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:41:32**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 01:55:19

US3462116

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:41:32

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'un UNK 2004'	(b) (4), (b) (6)	13 Aug 2020 01:55:19

**US3462116**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:41:32**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 01:55:19

**US3462116**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:41:32**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered 'Jan 2003'	System	13 Aug 2020 01:55:19

**US3462116**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:41:32**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered '2003'	System	13 Aug 2020 01:55:19

**US3462116**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:41:32**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered 'Jan 2004'	System	13 Aug 2020 01:55:19



**US3462116**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:41:32**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered '2004'	System	13 Aug 2020 01:55:19

US3462116

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:41:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User coded data point as SOC: Endocrine disorders, HLT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 01:57:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 01:57:14
Data point term sent to Coder	System	13 Aug 2020 01:56:10
User entered 'Hypothyroidism'	(b) (4), (b) (6)	13 Aug 2020 01:55:38

US3462116

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:41:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'un UNK 2004'	(b) (4), (b) (6)	13 Aug 2020 01:55:38

US3462116

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:41:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 01:55:38

**US3462116**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:41:32**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 01:55:38

US3462116

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:41:32

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 01:55:38

US3462116

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:41:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 01:55:38

**US3462116**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:41:32**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered 'Jan 2004'	System	13 Aug 2020 01:55:38



**US3462116**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:41:32**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered '2004'	System	13 Aug 2020 01:55:38

**US3462116**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:41:32**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered empty.	System	13 Aug 2020 01:55:38

**US3462116**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:41:32**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered empty.	System	13 Aug 2020 01:55:38

US3462116

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:41:32

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Ankle osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 12:44:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 12:44:44
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Arthritis, LLT: Arthritis - version MedDRA\\23.0.	Coder Import (b) (4)	27 Oct 2020 15:14:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	27 Oct 2020 15:14:43
Data point term sent to Coder	System	13 Aug 2020 01:57:12
User entered 'Right Ankle Arthritis'	(b) (4), (b) (6)	13 Aug 2020 01:56:11

**US3462116**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:41:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'un UNK 1997'	(b) (4), (b) (6)	13 Aug 2020 01:56:11

**US3462116**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:41:32**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 01:56:11

**US3462116**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:41:32**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 01:56:11

US3462116

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:41:32

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'un UNK 2006'	(b) (4), (b) (6)	13 Aug 2020 01:56:11



**US3462116**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:41:32**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 01:56:11

**US3462116**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:41:32**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered 'Jan 1997'	System	13 Aug 2020 01:56:11

**US3462116**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:41:32**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered '1997'	System	13 Aug 2020 01:56:11

**US3462116**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:41:32**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered 'Jan 2006'	System	13 Aug 2020 01:56:11

**US3462116**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:41:32**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered '2006'	System	13 Aug 2020 01:56:11

US3462116

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:41:32

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
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 protrusion, LLT: Ruptured intervertebral disc - version MedDRA\\23.0.	Coder Import (b) (4)	20 Sep 2020 14:00:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	20 Sep 2020 14:00:45
Data point term sent to Coder	System	13 Aug 2020 01:57:11
User entered 'Ruptured L5'	(b) (4), (b) (6)	13 Aug 2020 01:56:34

US3462116

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:41:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'un UNK 1991'	(b) (4), (b) (6)	13 Aug 2020 01:56:34

US3462116

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:41:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 01:56:34



**US3462116**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:41:32**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 01:56:34

**US3462116**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:41:32**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'un UNK 1991'	(b) (4), (b) (6)	13 Aug 2020 01:56:34

**US3462116**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:41:32**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 01:56:34

**US3462116**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:41:32**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered 'Jan 1991'	System	13 Aug 2020 01:56:34

**US3462116**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:41:32**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered '1991'	System	13 Aug 2020 01:56:34

**US3462116**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:41:32**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered 'Jan 1991'	System	13 Aug 2020 01:56:34

**US3462116**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:41:32**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered '1991'	System	13 Aug 2020 01:56:34

US3462116

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:41:32

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
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 protrusion, LLT: Ruptured intervertebral disc - version MedDRA\\23.0.	Coder Import (b) (4)	20 Sep 2020 14:00:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	20 Sep 2020 14:00:45
Data point term sent to Coder	System	13 Aug 2020 01:57:12
User entered 'Ruptured L6'	(b) (4), (b) (6)	13 Aug 2020 01:57:05



US3462116

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:41:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'un UNK 2006'	(b) (4), (b) (6)	13 Aug 2020 01:57:05

**US3462116**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:41:32**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 01:57:05

US3462116

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:41:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 01:57:05

US3462116

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:41:32

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'un UNK 2006'	(b) (4), (b) (6)	13 Aug 2020 01:57:05

US3462116

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:41:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 01:57:05

**US3462116**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:41:32**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered 'Jan 2006'	System	13 Aug 2020 01:57:05

**US3462116**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:41:32**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered '2006'	System	13 Aug 2020 01:57:05

**US3462116**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:41:32**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered 'Jan 2006'	System	13 Aug 2020 01:57:05



**US3462116**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:41:32**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered '2006'	System	13 Aug 2020 01:57:05

US3462116

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:41:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Contraceptive methods female, PT: Female sterilisation, LLT: Tubal ligation - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 01:59:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 01:59:15
Data point term sent to Coder	System	13 Aug 2020 01:58:12
User entered 'Tubal Ligation'	(b) (4), (b) (6)	13 Aug 2020 01:57:28

US3462116

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:41:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'un Nov 2005'	(b) (4), (b) (6)	13 Aug 2020 01:57:28

US3462116

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:41:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 01:57:28

**US3462116**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:41:32**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 01:57:28

**US3462116**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:41:32**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'un Nov 2005'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 01:57:28

**US3462116**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:41:32**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 01:57:28

**US3462116**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:41:32**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered 'Nov 2005'	System	13 Aug 2020 01:57:28



**US3462116**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:41:32**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered '2005'	System	13 Aug 2020 01:57:28

**US3462116**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:41:32**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered 'Nov 2005'	System	13 Aug 2020 01:57:28

**US3462116**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:41:32**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered '2005'	System	13 Aug 2020 01:57:28

US3462116

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:41:32

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Ankle operation, LLT: Ankle operation - version MedDRA\23.0.	Coder Import (b) (4)	18 Nov 2020 10:39:02
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	18 Nov 2020 10:39:02
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 19:11:41
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' answered with 'Ankle joint fusion secondary to ankle arthritis note in past medical history' (Site from DM).	Danuel Hamlin (b) (4)	04 Nov 2020 15:46:50
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 08:16:44
Data point term sent to Coder	System	13 Aug 2020 01:58:12
User entered 'Right Ankle Joint Fusion'	(b) (4), (b) (6)	13 Aug 2020 01:57:52

US3462116

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:41:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'un UNK 2016'	(b) (4), (b) (6)	13 Aug 2020 01:57:52

US3462116

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:41:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 01:57:52

**US3462116**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:41:32**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 01:57:52

**US3462116**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:41:32**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'un UNK 2016'	(b) (4), (b) (6)	13 Aug 2020 01:57:52



**US3462116**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:41:32**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 01:57:52

**US3462116**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:41:32**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered 'Jan 2016'	System	13 Aug 2020 01:57:52

**US3462116**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:41:32**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered '2016'	System	13 Aug 2020 01:57:52

**US3462116**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:41:32**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered 'Jan 2016'	System	13 Aug 2020 01:57:52

**US3462116**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:41:32**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered '2016'	System	13 Aug 2020 01:57:52

US3462116

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:41:32

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Spine and spinal cord therapeutic procedures, PT: Intervertebral disc operation, LLT: Lumbar discectomy - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 02:00:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 02:00:16
Data point term sent to Coder	System	13 Aug 2020 01:59:13
User entered 'Lumbar Discectomy'	(b) (4), (b) (6)	13 Aug 2020 01:58:17

**US3462116**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:41:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'un UNK 1991'	(b) (4), (b) (6)	13 Aug 2020 01:58:17

US3462116

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:41:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 01:58:17



**US3462116**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:41:32**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 01:58:17

US3462116

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:41:32

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User closed query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this procedure. Note, procedures/surgeries typically have the same start/stop date. Please correct dates or provide explanation for the Med History duration. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:20:59
Query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this procedure. Note, procedures/surgeries typically have the same start/stop date. Please correct dates or provide explanation for the Med History duration. ' answered with 'Corrected' (Site from DM).	Danuel Hamlin (b) (4)	04 Nov 2020 15:50:03
User entered 'UN UNK 1991' reason for change: Data Entry Error	Danuel Hamlin (b) (4)	04 Nov 2020 15:49:50
User opened query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this procedure. Note, procedures/surgeries typically have the same start/stop date. Please correct dates or provide explanation for the Med History duration. ' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 08:17:03
User entered 'un UNK 2006'		13 Aug 2020 01:58:17

US3462116

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:41:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 01:58:17

**US3462116**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:41:32**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered 'Jan 1991'	System	13 Aug 2020 01:58:17

**US3462116**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:41:32**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered '1991'	System	13 Aug 2020 01:58:17

**US3462116**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:41:32**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered 'Jan 1991'	System	04 Nov 2020 15:49:50
User entered 'Jan 2006'	System	13 Aug 2020 01:58:17

**US3462116**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:41:32**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered '1991'	System	04 Nov 2020 15:49:50
User entered '2006'	System	13 Aug 2020 01:58:17

US3462116

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:41:32

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Tonsillar therapeutic procedures, PT: Tonsillectomy, LLT: Tonsillectomy - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 02:00:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 02:00:16
Data point term sent to Coder	System	13 Aug 2020 01:59:13
User entered 'Tonsillectomy'	(b) (4), (b) (6)	13 Aug 2020 01:58:44



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Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:41:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'un UNK 1981'	(b) (4), (b) (6)	13 Aug 2020 01:58:44

US3462116

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:41:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 01:58:44

**US3462116**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 17:41:32**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 01:58:44

**US3462116**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 17:41:32**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'un UNK 1981'	(b) (4), (b) (6)	13 Aug 2020 01:58:44

**US3462116**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 17:41:32**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 01:58:44

**US3462116**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 17:41:32**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered 'Jan 1981'	System	13 Aug 2020 01:58:44

**US3462116**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 17:41:32**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered '1981'	System	13 Aug 2020 01:58:44

**US3462116**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 17:41:32**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered 'Jan 1981'	System	13 Aug 2020 01:58:44



**US3462116**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 17:41:32**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered '1981'	System	13 Aug 2020 01:58:44

US3462116

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:41:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Spine and spinal cord therapeutic procedures, PT: Intervertebral disc operation, LLT: Lumbar discectomy - version MedDRA\\23.0.	Coder Import (b) (4)	04 Nov 2020 15:51:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Nov 2020 15:51:25
Data point term sent to Coder	System	04 Nov 2020 15:50:40
User entered 'Lumbar Disectomy'	Danuel Hamlin (b) (4)	04 Nov 2020 15:50:33

**US3462116**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 17:41:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'un UNK 2006'	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 15:50:33

**US3462116**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 17:41:32**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 15:50:33

**US3462116**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 17:41:32**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 15:50:33

US3462116

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:41:32

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'un UNK 2006'	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 15:50:33

US3462116

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:41:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 15:50:33

**US3462116**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 17:41:32**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered 'Jan 2006'	System	04 Nov 2020 15:50:33



**US3462116**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 17:41:32**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered '2006'	System	04 Nov 2020 15:50:33

**US3462116**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 17:41:32**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered 'Jan 2006'	System	04 Nov 2020 15:50:33

**US3462116**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 17:41:32**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered '2006'	System	04 Nov 2020 15:50:33

US3462116

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:41:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type II diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4)	25 Nov 2020 02:27:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Nov 2020 02:27:04
Data point term sent to Coder	System	25 Nov 2020 02:26:05
User entered 'Type II Diabetes'	Danuel Hamlin (b) (4)	25 Nov 2020 02:25:19

US3462116

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:41:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'un UNK 2019'	(b) (4) Danuel Hamlin (b) (4)	25 Nov 2020 02:25:19

**US3462116**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 17:41:32**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	25 Nov 2020 02:25:19

**US3462116**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 17:41:32**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	25 Nov 2020 02:25:19

**US3462116**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 17:41:32**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	25 Nov 2020 02:25:19



US3462116

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:41:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	25 Nov 2020 02:25:19

**US3462116**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 17:41:32**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered 'Jan 2019'	System	25 Nov 2020 02:25:19

**US3462116**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 17:41:32**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered '2019'	System	25 Nov 2020 02:25:19

**US3462116**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 17:41:32**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered empty.	System	25 Nov 2020 02:25:19

**US3462116**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 17:41:32**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered empty.	System	25 Nov 2020 02:25:19

US3462116

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:41:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Bronchospasm, LLT: Bronchospasm - version MedDRA\\23.0.	Coder Import (b) (4)	25 Nov 2020 06:53:10
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	25 Nov 2020 06:53:10
Data point term sent to Coder	System	25 Nov 2020 02:26:03
User entered 'Exertional Bronchospasm'	Danuel Hamlin (b) (4)	25 Nov 2020 02:25:48

**US3462116**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 17:41:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'un UNK 2004'	(b) (4) Danuel Hamlin (b) (4)	25 Nov 2020 02:25:48

**US3462116**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 17:41:32**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	25 Nov 2020 02:25:48



**US3462116**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 17:41:32**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	25 Nov 2020 02:25:48

**US3462116**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 17:41:32**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered empty.	Danuel Hamlin (b) (4)	25 Nov 2020 02:25:48

US3462116

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:41:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	25 Nov 2020 02:25:48

**US3462116**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 17:41:32**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered 'Jan 2004'	System	25 Nov 2020 02:25:48

**US3462116**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 17:41:32**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered '2004'	System	25 Nov 2020 02:25:48

**US3462116**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 17:41:32**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered empty.	System	25 Nov 2020 02:25:48

**US3462116**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 17:41:32**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered empty.	System	25 Nov 2020 02:25:48

US3462116

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:41:32

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User coded data point as SOC: Psychiatric disorders, HLT: Psychiatric disorders NEC, HLT: Substance related and addictive disorders, PT: Drug abuse, LLT: Drug abuse - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Mar 2021 11:29:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Mar 2021 11:29:49
User signature succeeded.	Gregg Lucksinger (b) (4) (b) (4)	19 Feb 2021 19:46:09
Data point term sent to Coder	System	15 Feb 2021 21:50:28
User entered 'METHAMPHETAMINE ABUSE 1993-2003'	(b) (4), (b) (6)  (b) (4)	15 Feb 2021 21:50:23



**US3462116**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 17:41:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
User entered 'un UNK 1993'	(b) (4), (b) (6)	15 Feb 2021 21:50:23

**US3462116**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 17:41:32**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
User entered '0'	(b) (4), (b) (6)	15 Feb 2021 21:50:23

**US3462116**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 17:41:32**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 21:50:23

**US3462116**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 17:41:32**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
User entered 'un UNK 2003'	(b) (4), (b) (6)	15 Feb 2021 21:50:23

**US3462116**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 17:41:32**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
User entered '0'	(b) (4), (b) (6)	15 Feb 2021 21:50:23

**US3462116**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 17:41:32**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered 'Jan 1993'	System	15 Feb 2021 21:50:23

**US3462116**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 17:41:32**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered '1993'	System	15 Feb 2021 21:50:23

**US3462116**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 17:41:32**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered 'Jan 2003'	System	15 Feb 2021 21:50:23



**US3462116**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 17:41:32**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered '2003'	System	15 Feb 2021 21:50:23

US3462116

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:41:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 21:21:45
User coded data point as SOC: Cardiac disorders, HLT: Myocardial disorders, HLT: Cardiomyopathies, PT: Cardiomyopathy, LLT: Cardiomyopathy - version MedDRA\\23.0.	Coder Import (b) (4)	24 Feb 2021 17:00:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Feb 2021 17:00:59
Data point term sent to Coder	System	24 Feb 2021 17:00:42
User entered 'FAMILIAL CARDIOMYOPATHY'	(b) (4), (b) (6)	24 Feb 2021 17:00:31

US3462116

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:41:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 21:21:45
User closed query 'Start date is after date of Informed Consent. Please correct.' (Site from System).	(b) (4)	01 Apr 2021 22:43:53
User entered 'un UNK 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Apr 2021 22:43:53
Comment added 'added from AE Report'.		24 Feb 2021 17:03:07
User opened query 'Start date is after date of Informed Consent. Please correct.' (Site from System).	System	24 Feb 2021 17:02:29
User entered '05 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 17:02:29
User closed query 'Start date is after date of Informed Consent. Please correct.' (Site from System).		24 Feb 2021 17:02:14
User entered 'un UNK 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 17:02:14
User opened query 'Start date is after date of Informed Consent. Please correct.' (Site from System).	System	24 Feb 2021 17:00:31
User entered '05 Sep 2020'	(b) (4), (b) (6)	24 Feb 2021 17:00:31

US3462116

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:41:32

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 21:21:45
User closed query 'Start date completely unknown is checked, however Start date has been provided. Please correct.' (Site from System).	(b) (4) System	24 Feb 2021 17:02:29
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 17:02:29
User opened query 'Start date completely unknown is checked, however Start date has been provided. Please correct.' (Site from System).	System	24 Feb 2021 17:02:14
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 17:02:14
User entered '0'		24 Feb 2021 17:00:31

**US3462116**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 17:41:32**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 21:21:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:00:31

**US3462116**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 17:41:32**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 21:21:45
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:00:31

**US3462116**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 17:41:32**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 21:21:45
User entered '0'	(b) (4) (u) (4), (b) (6)	24 Feb 2021 17:00:31

**US3462116**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 17:41:32**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered 'Jan 2020'	System	01 Apr 2021 22:43:53
User entered 'Sep 2020'	System	24 Feb 2021 17:02:29
User entered 'Jan 2020'	System	24 Feb 2021 17:02:14
User entered 'Sep 2020'	System	24 Feb 2021 17:00:31



**US3462116**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 17:41:32**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered '2020'	System	24 Feb 2021 17:00:31

**US3462116**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 17:41:32**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered empty.	System	24 Feb 2021 17:00:31

**US3462116**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 17:41:32**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered empty.	System	24 Feb 2021 17:00:31

US3462116

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:41:32

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User closed query 'Per DM CLR: Please verify the type of DIABETIC NEUROPATHY (i.e. sensory or motor) and location (arms, legs, 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).		06 Apr 2021 12:23:32
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 21:21:45
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Chronic polyneuropathies, PT: Diabetic neuropathy, LLT: Diabetic peripheral neuropathy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	05 Apr 2021 20:45:38
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 20:45:38
Data point term sent to Coder	System	05 Apr 2021 20:44:47
Query 'Per DM CLR: Please verify the type of DIABETIC NEUROPATHY (i.e. sensory or motor) and location (arms, legs, 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).	(b) (4), (b) (6)	05 Apr 2021 20:44:21
Coding entries removed.		05 Apr 2021 20:43:53
User entered 'Sensory DIABETIC NEUROPATHY Bilateral Feet' reason for change: Data Entry Error		05 Apr 2021 20:43:53
User opened query 'Per DM CLR: Please verify the type of DIABETIC NEUROPATHY (i.e. sensory or motor) and location (arms, legs, 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).		10 Mar 2021 02:58:01

US3462116

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:41:32

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Chronic polyneuropathies, PT: Diabetic neuropathy, LLT: Diabetic neuropathy - version MedDRA\\23.0.	Coder Import (b) (4)	02 Mar 2021 21:03:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Mar 2021 21:03:46
Data point term sent to Coder	System	02 Mar 2021 21:03:36
User entered 'Diabetic Neuropathy'	(b) (4), (b) (6)	02 Mar 2021 21:03:22

**US3462116**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 17:41:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 21:21:45
User entered 'un UNK 2019'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:03:22

**US3462116**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 17:41:32**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 21:21:45
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:03:22

**US3462116**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 17:41:32**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 21:21:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:03:22



**US3462116**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 17:41:32**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 21:21:45
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:03:22

**US3462116**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 17:41:32**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 21:21:45
User entered '0'	(b) (4) (u) (4), (b) (6)	02 Mar 2021 21:03:22

**US3462116**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 17:41:32**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered 'Jan 2019'	System	02 Mar 2021 21:03:22

**US3462116**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 17:41:32**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered '2019'	System	02 Mar 2021 21:03:22

**US3462116**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 17:41:32**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered empty.	System	02 Mar 2021 21:03:22

**US3462116**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 17:41:32**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered empty.	System	02 Mar 2021 21:03:22

US3462116

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:41:32

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
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: Pain in extremity, LLT: Foot pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Apr 2021 14:02:56
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Apr 2021 14:02:56
User signature succeeded.	Gregg Lucksinger (b) (4) (b) (4)	13 Apr 2021 00:44:54
Data point term sent to Coder	System	12 Apr 2021 18:54:48
Coding entries removed.	(b) (4), (b) (6)	12 Apr 2021 18:54:32
Signature has been broken.		12 Apr 2021 18:54:32
User entered 'CHRONIC FOOT PAIN bilateral' reason for change: Data Entry Error		12 Apr 2021 18:54:32
User signature succeeded.	Gregg Lucksinger (b) (4) (b) (4)	05 Apr 2021 21:21:45
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: Pain in extremity, LLT: Foot pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Mar 2021 00:12:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Mar 2021 00:12:53
Data point term sent to Coder	System	02 Mar 2021 21:04:39
User entered 'Chronic foot Pain'	(b) (4), (b) (6)	02 Mar 2021 21:03:44

**US3462116**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 17:41:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 21:21:45
User entered 'un UNK 2016'	(b) (4) (u) (4), (b) (6)	02 Mar 2021 21:03:44



**US3462116**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 17:41:32**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 21:21:45
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:03:44

**US3462116**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 17:41:32**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 21:21:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:03:44

**US3462116**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 17:41:32**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 21:21:45
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:03:44

**US3462116**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 17:41:32**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 21:21:45
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:03:44

**US3462116**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 17:41:32**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered 'Jan 2016'	System	02 Mar 2021 21:03:44

**US3462116**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 17:41:32**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered '2016'	System	02 Mar 2021 21:03:44

**US3462116**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 17:41:32**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered empty.	System	02 Mar 2021 21:03:44

**US3462116**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 17:41:32**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered empty.	System	02 Mar 2021 21:03:44



US3462116

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:41:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 21:21:45
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Skin and subcutaneous tissue disorders NEC, HLT: Skin and subcutaneous tissue ulcerations, PT: Diabetic ulcer, LLT: Diabetic ulcer - version MedDRA\\23.0.	Coder Import (b) (4)	04 Mar 2021 14:51:58
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	04 Mar 2021 14:51:58
Data point term sent to Coder	System	02 Mar 2021 21:05:39
User entered 'Diabetic Ulcers'	(b) (4), (b) (6)	02 Mar 2021 21:05:15

**US3462116**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 09 Jun 2021 17:41:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 21:21:45
User entered 'un UNK 2020'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:05:15

**US3462116**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 09 Jun 2021 17:41:32**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 21:21:45
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:05:15

**US3462116**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 09 Jun 2021 17:41:32**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 21:21:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:05:15

**US3462116**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 09 Jun 2021 17:41:32**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 21:21:45
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:05:15

**US3462116**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 09 Jun 2021 17:41:32**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 21:21:45
User entered '0'	(b) (4) (u) (4), (b) (6)	02 Mar 2021 21:05:15

**US3462116**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 09 Jun 2021 17:41:32**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered 'Jan 2020'	System	02 Mar 2021 21:05:15

**US3462116**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 09 Jun 2021 17:41:32**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered '2020'	System	02 Mar 2021 21:05:15



**US3462116**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 09 Jun 2021 17:41:32**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered empty.	System	02 Mar 2021 21:05:15

**US3462116**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 09 Jun 2021 17:41:32**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered empty.	System	02 Mar 2021 21:05:15

US3462116

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 01:59:52

US3462116

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '11 Aug 2020'	(b) (4), (b) (6)	13 Aug 2020 01:59:52

US3462116

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '10:58'	(b) (4), (b) (6)	13 Aug 2020 01:59:52

**US3462116**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:41:32**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered '11 Aug 2020 10:58'	System	13 Aug 2020 01:59:52

US3462116

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:32

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '173' cm	(b) (4) (b) (4), (b) (6)	13 Aug 2020 01:59:52
DataPoint set to visible.	System	11 Aug 2020 19:30:54

US3462116

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:32

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '108' kg	(b) (4) (b) (4), (b) (6)	13 Aug 2020 01:59:52
DataPoint set to visible.	System	11 Aug 2020 19:30:54



**US3462116**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:41:32**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
Amendment Manager: User entered '36.08540'	System	16 Sep 2020 23:51:55
User entered '36.1'	System	13 Aug 2020 01:59:52
DataPoint set to visible.	System	11 Aug 2020 19:30:54

US3462116

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:32

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered 'kg/m2'	System	13 Aug 2020 01:59:52
DataPoint set to visible.	System	11 Aug 2020 19:30:54

US3462116

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Danuel Hamlin (b) (4)	02 Oct 2020 22:26:01
User entered '97.5' F	(b) (4), (b) (6)	13 Aug 2020 01:59:52

US3462116

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered empty; reason for change Data Entry Error	(b) (4) Danuel Hamlin (b) (4)	02 Oct 2020 22:26:01
User entered 'Other (Other)'	(b) (4), (b) (6)	13 Aug 2020 01:59:52

US3462116

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered empty; reason for change Data Entry Error	(b) (4) Danuel Hamlin (b) (4)	02 Oct 2020 22:26:01
User entered 'Tympanic'	(b) (4), (b) (6)	13 Aug 2020 01:59:52

US3462116

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Danuel Hamlin (b) (4)	02 Oct 2020 22:26:01
User entered '90'	(b) (4), (b) (6)	13 Aug 2020 01:59:52

**US3462116**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:41:32**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered 'bpm'	System	13 Aug 2020 01:59:52

US3462116

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:32

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Danuel Hamlin (b) (4)	02 Oct 2020 22:26:01
User entered '16'	(b) (4), (b) (6)	13 Aug 2020 01:59:52



**US3462116**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:41:32**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered 'breaths/min'	System	13 Aug 2020 01:59:52

US3462116

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Danuel Hamlin (b) (4)	02 Oct 2020 22:26:01
User entered '140'	(b) (4), (b) (6)	13 Aug 2020 01:59:52

US3462116

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered 'mmHg'	System	13 Aug 2020 01:59:52

US3462116

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Danuel Hamlin (b) (4)	02 Oct 2020 22:26:01
User entered '84'	(b) (4), (b) (6)	13 Aug 2020 01:59:52

**US3462116**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:41:32**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User entered 'mmHg'	System	13 Aug 2020 01:59:52

**US3462116**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:41:32**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34

US3462116

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:32

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34

US3462116

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:41:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 02:00:05



US3462116

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:41:32

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	24 Sep 2020 11:28:22
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	14 Sep 2020 21:15:06
User entered '11 Aug 2020'	(b) (4), (b) (6)	13 Aug 2020 02:00:05

US3462116

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:41:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '11 Aug 2020'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 02:00:31

US3462116

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:41:32

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 02:00:31

**US3462116**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 17:41:32**

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'Surgically sterile (SURGICALLY STERILE)'	(b) (4), (b) (6)	13 Aug 2020 02:00:31

US3462116

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:41:32

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 02:00:31

US3462116

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:41:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User closed query 'Surgically sterile been entered, however date of surgery is missing. Please provide.' (Site from System).	(b) (4)	
User entered 'un Nov 2005' reason for change: Data Entry Error	System	13 Aug 2020 02:00:50
User opened query 'Surgically sterile been entered, however date of surgery is missing. Please provide.' (Site from System).	(b) (4), (b) (6)	13 Aug 2020 02:00:50
User entered empty.		
	System	13 Aug 2020 02:00:31
	(b) (4), (b) (6)	13 Aug 2020 02:00:31

US3462116

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:41:32

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 02:00:31

US3462116

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:41:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 02:00:31



US3462116

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:41:32

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 02:00:31

US3462116

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:32

[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 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 02:01:28

US3462116

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:32

**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 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 02:01:28

US3462116

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:32

**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 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 02:01:28

US3462116

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:32

**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 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 02:01:28

US3462116

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:32

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 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 02:01:28

US3462116

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:32

[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 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 02:01:28

US3462116

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:32

**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 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 02:01:28



US3462116

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:32

**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 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 02:01:28

US3462116

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:32

[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 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 02:01:28

US3462116

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:32

**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 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 02:01:28

US3462116

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:32

**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 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 02:01:28

**US3462116**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 09 Jun 2021 17:41:32**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 02:01:28

US3462116

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:32

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 02:01:28

US3462116

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:32

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'I'	(b) (4), (b) (6)	13 Aug 2020 02:01:28

US3462116

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:32

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 02:01:28



US3462116

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:32

**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 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 02:01:28

US3462116

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:32

[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 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 02:01:28

US3462116

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:32

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 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 02:01:28

US3462116

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:32

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 02:01:28

US3462116

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:32

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 02:01:28

US3462116

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:32

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:48:34
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 02:01:28

US3462116

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:41:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 13OCT2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Nov 2020 08:29:01
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 13OCT2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).		02 Nov 2020 08:26:53
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	11 Aug 2020 19:31:13

US3462116

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:41:32

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '11 Aug 2020'	(b) (4) Danuel Hamlin (b) (4)	11 Aug 2020 19:31:13



US3462116

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:41:32

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'Clinic (Clinic)'	(b) (4) Danuel Hamlin (b) (4)	11 Aug 2020 19:31:13

**US3462116**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:41:32**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User entered 'VISIT1'	System	11 Aug 2020 19:31:13

US3462116

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:41:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '11 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 18:29:15

US3462116

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:41:32

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 03:36:41
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:36:41
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Aug 2020 18:29:15
User entered '103130' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 18:29:15

US3462116

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:41:32

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 18:29:15

US3462116

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:41:32

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 02:01:59

US3462116

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:41:32

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 02:01:59

**US3462116**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 17:41:32**

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 02:01:59



US3462116

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:41:32

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 02:01:59

US3462116

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:41:32

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 02:01:59

US3462116

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:41:32

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 20:32:54
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:17:42
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:32:38

US3462116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:41:32

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Danuel Hamlin (b) (4)	02 Oct 2020 22:25:41
User entered '173' cm	(b) (4), (b) (6)	13 Aug 2020 02:04:17

US3462116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:41:32

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Danuel Hamlin (b) (4)	02 Oct 2020 22:25:41
User entered '108' kg	(b) (4), (b) (6)	13 Aug 2020 02:04:17

US3462116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:41:32

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Danuel Hamlin (b) (4)	02 Oct 2020 22:25:41
User entered '173' cm	(b) (4), (b) (6)	13 Aug 2020 02:04:17

US3462116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:41:32

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Danuel Hamlin (b) (4)	02 Oct 2020 22:25:41
User entered '108' kg	(b) (4), (b) (6)	13 Aug 2020 02:04:17

**US3462116**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:41:32**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User accepted default value 'Pre-Dose (PREDOSE)'		13 Aug 2020 02:04:17



US3462116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 02:04:17

US3462116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '11 Aug 2020'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 02:04:17

US3462116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '10:58'	(b) (4), (b) (6)	13 Aug 2020 02:04:17

**US3462116**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:41:32**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User entered '11 Aug 2020 10:58'	System	13 Aug 2020 02:04:17

US3462116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '97.5' F	(b) (4), (b) (6)	13 Aug 2020 02:04:17

US3462116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'Other (Other)'	(b) (4), (b) (6)	13 Aug 2020 02:04:17

US3462116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'Tympanic'	(b) (4), (b) (6)	13 Aug 2020 02:04:17

US3462116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '90'	(b) (4), (b) (6)	13 Aug 2020 02:04:17



**US3462116**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:41:32**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User entered 'bpm'	System	13 Aug 2020 02:04:17

US3462116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:32

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '16'	(b) (4), (b) (6)	13 Aug 2020 02:04:17

**US3462116**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:41:32**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User entered 'breaths/min'	System	13 Aug 2020 02:04:17

US3462116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '140'	(b) (4), (b) (6)	13 Aug 2020 02:04:17

**US3462116**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:41:32**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User entered 'mmHg'	System	13 Aug 2020 02:04:17

US3462116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '84'	(b) (4), (b) (6)	13 Aug 2020 02:04:17

**US3462116**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:41:32**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User entered 'mmHg'	System	13 Aug 2020 02:04:17

US3462116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:41:32

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Danuel Hamlin (b) (4)	02 Oct 2020 22:25:41
User entered '173' cm	(b) (4), (b) (6)	13 Aug 2020 02:04:17



US3462116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:41:32

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Danuel Hamlin (b) (4)	02 Oct 2020 22:25:41
User entered '108' kg	(b) (4), (b) (6)	13 Aug 2020 02:04:17

US3462116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:32

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User accepted default value 'Post-Dose (POSTDOSE)'		13 Aug 2020 02:04:17

US3462116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 02:04:17

US3462116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '11 Aug 2020'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 02:04:17

US3462116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
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) (4), (b) (6)	18 Aug 2020 12:13:01
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).		13 Aug 2020 02:04:17
User entered '12:53'	(b) (4), (b) (6)	13 Aug 2020 02:04:17

**US3462116**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:41:32**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User entered '11 Aug 2020 12:53'	System	13 Aug 2020 02:04:17

US3462116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '97.3' F	(b) (4), (b) (6)	13 Aug 2020 02:04:17

US3462116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'Other (Other)'	(b) (4), (b) (6)	13 Aug 2020 02:04:17



US3462116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'Tympanic'	(b) (4), (b) (6)	13 Aug 2020 02:04:17

US3462116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '95'	(b) (4), (b) (6)	13 Aug 2020 02:04:17

**US3462116**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:41:32**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User entered 'bpm'	System	13 Aug 2020 02:04:17

US3462116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:32

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '16'	(b) (4), (b) (6)	13 Aug 2020 02:04:17

US3462116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User entered 'breaths/min'	System	13 Aug 2020 02:04:17

US3462116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '152'	(b) (4), (b) (6)	13 Aug 2020 02:04:17

**US3462116**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:41:32**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User entered 'mmHg'	System	13 Aug 2020 02:04:17

US3462116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '92'	(b) (4), (b) (6)	13 Aug 2020 02:04:17



**US3462116**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:41:32**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User entered 'mmHg'	System	13 Aug 2020 02:04:17

US3462116

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:41:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 02:04:54

US3462116

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:41:32

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '11 Aug 2020'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 02:04:54

US3462116

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:41:32

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	11 Aug 2020 19:31:39

US3462116

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:41:32

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	11 Aug 2020 19:31:39

US3462116

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:41:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered empty.	Danuel Hamlin (b) (4)	11 Aug 2020 19:31:39

**US3462116**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:41:32**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User entered 'MRNA-1273 OR PLACEBO'	System	11 Aug 2020 19:31:39

US3462116

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:41:32

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '11 Aug 2020'	(b) (4) Danuel Hamlin (b) (4)	11 Aug 2020 19:31:39



US3462116

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:41:32

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '12:22'	(b) (4) Danuel Hamlin (b) (4)	11 Aug 2020 19:31:39

**US3462116**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:41:32**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User entered '11 Aug 2020 12:22'	System	11 Aug 2020 19:31:39

US3462116

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:41:32

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'Right Arm (RIGHT ARM)' reason for change: Data Entry Error	(b) (4) Danuel Hamlin (b) (4)	10 Nov 2020 02:34:17
User entered 'Left Arm (LEFT ARM)'	Danuel Hamlin (b) (4)	11 Aug 2020 19:31:39

US3462116

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:41:32

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User entered 'ONCE'	System	11 Aug 2020 19:31:39

US3462116

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:41:32

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User entered 'INTRAMUSCULAR'	System	11 Aug 2020 19:31:39

US3462116

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 02:05:12

US3462116

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:32

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '11 Aug 2020'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 02:05:12

US3462116

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:32

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '11:50'	(b) (4), (b) (6)	13 Aug 2020 02:05:12



**US3462116**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:41:32**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User entered '11 Aug 2020 11:50'	System	13 Aug 2020 02:05:12

US3462116

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:41:32

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '11 Aug 2020'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 02:05:43

**US3462116**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:41:32**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		13 Aug 2020 02:05:43

US3462116

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:41:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 02:05:43

US3462116

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:41:32

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '11:52'	(b) (4), (b) (6)	13 Aug 2020 02:05:43

**US3462116**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:41:32**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User entered '11 Aug 2020 11:52'	System	13 Aug 2020 02:05:43

**US3462116**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:41:32**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		13 Aug 2020 02:05:43

US3462116

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:41:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	09 Oct 2020 20:33:13
User entered 'Yes (Y)'		13 Aug 2020 02:05:43



US3462116

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:41:32

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	09 Oct 2020 20:33:13
User entered '11:52'		13 Aug 2020 02:05:43

**US3462116**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:41:32**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User entered empty.	System	09 Oct 2020 20:33:13
User entered '11 Aug 2020 11:52'	System	13 Aug 2020 02:05:43

US3462116

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:41:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 02:05:48

**US3462116**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:41:32**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User entered 'I'	System	13 Aug 2020 02:05:48

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
Data entry locked.	System	11 Aug 2020 19:31:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:41:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-11T12:55:01', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'ed9b08e9-5f5c-40c2-b116-07a66b66abb9'	System	11 Aug 2020 19:55:24
User entered 'Yes (Y)'	System	11 Aug 2020 19:55:24

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:41:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-11T12:55:09', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'ed9b08e9-5f5c-40c2-b116-07a66b66abb9'	System	11 Aug 2020 19:55:24
User entered '93.7'	System	11 Aug 2020 19:55:24

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:41:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-11T12:55:15', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'ed9b08e9-5f5c-40c2-b116-07a66b66abb9'	System	11 Aug 2020 19:55:24
User entered 'No (N)'	System	11 Aug 2020 19:55:24



US3462116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:41:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-11T12:55:22', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'ed9b08e9-5f5c-40c2-b116-07a66b66abb9'	System	11 Aug 2020 19:55:24
User entered '11 Aug 2020 12:55'	System	11 Aug 2020 19:55:24

**US3462116**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 17:41:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '11 Aug 2020 12:42'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:41:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '11 Aug 2020 15:12'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
Data entry locked.	System	11 Aug 2020 19:31:39
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:41:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-11T16:09:01', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '10135816-9a8a-4172-948a-beb77a165989'	System	11 Aug 2020 23:10:25
User entered 'Yes (Y)'	System	11 Aug 2020 23:10:25

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:41:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-11T16:10:09', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '10135816-9a8a-4172-948a-beb77a165989'	System	11 Aug 2020 23:10:25
User entered '97.4'	System	11 Aug 2020 23:10:25

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:41:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-11T16:10:12', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '10135816-9a8a-4172-948a-beb77a165989'	System	11 Aug 2020 23:10:25
User entered 'No (N)'	System	11 Aug 2020 23:10:25

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:41:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-11T16:10:21', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '10135816-9a8a-4172-948a-beb77a165989'	System	11 Aug 2020 23:10:25
User entered '11 Aug 2020 16:10'	System	11 Aug 2020 23:10:25



**US3462116**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 17:41:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '11 Aug 2020 16:07'	System	11 Aug 2020 19:31:39

**US3462116**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 17:41:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
Data entry locked.	System	11 Aug 2020 19:31:39
User entered 'Day 2'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:41:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-12T12:40:48', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '29389baf-3cfe-43d0-8ef1-66e88e5cc930'	System	12 Aug 2020 19:41:08
User entered 'Yes (Y)'	System	12 Aug 2020 19:41:08

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:41:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-12T12:40:56', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '29389baf-3cfe-43d0-8ef1-66e88e5cc930'	System	12 Aug 2020 19:41:08
User entered '97.4'	System	12 Aug 2020 19:41:08

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:41:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-12T12:41:00', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '29389baf-3cfe-43d0-8ef1-66e88e5cc930'	System	12 Aug 2020 19:41:08
User entered 'No (N)'	System	12 Aug 2020 19:41:08

**US3462116**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 17:41:32**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-12T12:41:04', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '29389baf-3cfe-43d0-8ef1-66e88e5cc930'	System	12 Aug 2020 19:41:08
User entered '12 Aug 2020 12:41'	System	12 Aug 2020 19:41:08

**US3462116**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 17:41:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 19:31:39



US3462116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:41:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
Data entry locked.	System	11 Aug 2020 19:31:39
User entered 'Day 3'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:41:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-13T12:08:21', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '964bea8c-a044-4bae-b7a7-15d179e356be'	System	13 Aug 2020 19:08:33
User entered 'Yes (Y)'	System	13 Aug 2020 19:08:33

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:41:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-13T12:08:26', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '964bea8c-a044-4bae-b7a7-15d179e356be'	System	13 Aug 2020 19:08:33
User entered '98.0'	System	13 Aug 2020 19:08:33

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:41:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-13T12:08:29', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '964bea8c-a044-4bae-b7a7-15d179e356be'	System	13 Aug 2020 19:08:33
User entered 'No (N)'	System	13 Aug 2020 19:08:33

**US3462116**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 17:41:32**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-13T12:08:32', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '964bea8c-a044-4bae-b7a7-15d179e356be'	System	13 Aug 2020 19:08:33
User entered '13 Aug 2020 12:08'	System	13 Aug 2020 19:08:33

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:41:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:41:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 19:31:39



US3462116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
Data entry locked.	System	11 Aug 2020 19:31:39
User entered 'Day 4'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:41:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-14T14:59:40', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'ba9b18b9-230d-48e4-9697-155c59321959'	System	14 Aug 2020 21:59:53
User entered 'Yes (Y)'	System	14 Aug 2020 21:59:53

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:41:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-14T14:59:45', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'ba9b18b9-230d-48e4-9697-155c59321959'	System	14 Aug 2020 21:59:53
User entered '97.5'	System	14 Aug 2020 21:59:53

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:41:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-14T14:59:47', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'ba9b18b9-230d-48e4-9697-155c59321959'	System	14 Aug 2020 21:59:53
User entered 'No (N)'	System	14 Aug 2020 21:59:53

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:41:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-14T14:59:50', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'ba9b18b9-230d-48e4-9697-155c59321959'	System	14 Aug 2020 21:59:53
User entered '14 Aug 2020 14:59'	System	14 Aug 2020 21:59:53

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:41:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:41:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
Data entry locked.	System	11 Aug 2020 19:31:39
User entered 'Day 5'	System	11 Aug 2020 19:31:39



US3462116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:41:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-15T12:00:36', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '1f17371a-1836-40ec-b937-b85eb76b79c7'	System	15 Aug 2020 19:00:49
User entered 'Yes (Y)'	System	15 Aug 2020 19:00:49

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:41:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-15T12:00:41', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '1f17371a-1836-40ec-b937-b85eb76b79c7'	System	15 Aug 2020 19:00:49
User entered '98.0'	System	15 Aug 2020 19:00:49

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:41:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-15T12:00:44', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '1f17371a-1836-40ec-b937-b85eb76b79c7'	System	15 Aug 2020 19:00:49
User entered 'No (N)'	System	15 Aug 2020 19:00:49

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:41:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-15T12:00:47', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '1f17371a-1836-40ec-b937-b85eb76b79c7'	System	15 Aug 2020 19:00:49
User entered '15 Aug 2020 12:00'	System	15 Aug 2020 19:00:49

**US3462116**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 17:41:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 19:31:39

**US3462116**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 17:41:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
Data entry locked.	System	11 Aug 2020 19:31:39
User entered 'Day 6'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:41:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-16T14:50:59', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'acf93b17-d577-49c7-b5a9-71e5b0b5d9d5'	System	16 Aug 2020 21:51:10
User entered 'Yes (Y)'	System	16 Aug 2020 21:51:10



US3462116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:41:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-16T14:51:03', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'acf93b17-d577-49c7-b5a9-71e5b0b5d9d5'	System	16 Aug 2020 21:51:10
User entered '97.6'	System	16 Aug 2020 21:51:10

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:41:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-16T14:51:05', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'acf93b17-d577-49c7-b5a9-71e5b0b5d9d5'	System	16 Aug 2020 21:51:10
User entered 'No (N)'	System	16 Aug 2020 21:51:10

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:41:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-16T14:51:07', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'acf93b17-d577-49c7-b5a9-71e5b0b5d9d5'	System	16 Aug 2020 21:51:10
User entered '16 Aug 2020 14:51'	System	16 Aug 2020 21:51:10

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:41:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 19:31:39

**US3462116**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 17:41:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
Data entry locked.	System	11 Aug 2020 19:31:39
User entered 'Day 7'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:41:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-17T12:17:59', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'f7424613-1d4a-4a37-9860-f8c9c77294ae'	System	17 Aug 2020 19:18:16
User entered 'Yes (Y)'	System	17 Aug 2020 19:18:16

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:41:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-17T12:18:05', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'f7424613-1d4a-4a37-9860-f8c9c77294ae'	System	17 Aug 2020 19:18:16
User entered '97.8'	System	17 Aug 2020 19:18:16



US3462116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:41:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-17T12:18:07', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'f7424613-1d4a-4a37-9860-f8c9c77294ae'	System	17 Aug 2020 19:18:16
User entered 'No (N)'	System	17 Aug 2020 19:18:16

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:41:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-17T12:18:10', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'f7424613-1d4a-4a37-9860-f8c9c77294ae'	System	17 Aug 2020 19:18:16
User entered '17 Aug 2020 12:18'	System	17 Aug 2020 19:18:16

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:41:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:41:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
Data entry locked.	System	11 Aug 2020 19:31:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:41:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-11T12:56:14', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'af33352b-d932-4ae8-a906-605493471ec7'	System	11 Aug 2020 19:56:42
User entered 'None (1)'	System	11 Aug 2020 19:56:42

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:41:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-11T12:56:20', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'af33352b-d932-4ae8-a906-605493471ec7'	System	11 Aug 2020 19:56:42
User entered 'No (N)'	System	11 Aug 2020 19:56:42

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:41:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-11T12:56:24', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'af33352b-d932-4ae8-a906-605493471ec7'	System	11 Aug 2020 19:56:42
User entered 'No (N)'	System	11 Aug 2020 19:56:42



US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:41:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-11T12:56:28', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'af33352b-d932-4ae8-a906-605493471ec7'	System	11 Aug 2020 19:56:42
User entered 'None (1)'	System	11 Aug 2020 19:56:42

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:41:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-11T12:56:37', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'af33352b-d932-4ae8-a906-605493471ec7'	System	11 Aug 2020 19:56:42
User entered '11 Aug 2020 12:56'	System	11 Aug 2020 19:56:42

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:41:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '11 Aug 2020 12:42'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:41:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '11 Aug 2020 15:12'	System	11 Aug 2020 19:31:39

**US3462116**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
Data entry locked.	System	11 Aug 2020 19:31:39
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:41:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-11T16:10:44', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'b76f9470-e03c-4ef5-8e77-073ed59c3a1d'	System	11 Aug 2020 23:12:17
User entered 'Does not interfere with activity (2)'	System	11 Aug 2020 23:12:17

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:41:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-11T16:10:50', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'b76f9470-e03c-4ef5-8e77-073ed59c3a1d'	System	11 Aug 2020 23:12:17
User entered 'No (N)'	System	11 Aug 2020 23:12:17

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:41:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-11T16:10:55', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'b76f9470-e03c-4ef5-8e77-073ed59c3a1d'	System	11 Aug 2020 23:12:17
User entered 'Yes (Y)'	System	11 Aug 2020 23:12:17



US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:41:32

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-11T16:11:52', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'b76f9470-e03c-4ef5-8e77-073ed59c3a1d'	System	11 Aug 2020 23:12:17
User entered '4'	System	11 Aug 2020 23:12:17

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:41:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-11T16:12:08', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'b76f9470-e03c-4ef5-8e77-073ed59c3a1d'	System	11 Aug 2020 23:12:17
User entered 'None (1)'	System	11 Aug 2020 23:12:17

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:41:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-11T16:12:12', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'b76f9470-e03c-4ef5-8e77-073ed59c3a1d'	System	11 Aug 2020 23:12:17
User entered '11 Aug 2020 16:12'	System	11 Aug 2020 23:12:17

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:41:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '11 Aug 2020 16:07'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:41:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 19:31:39

**US3462116**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
Data entry locked.	System	11 Aug 2020 19:31:39
User entered 'Day 2'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:41:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-12T12:41:11', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '63d025dd-e862-40f6-9e45-fde1552c7d03'	System	12 Aug 2020 19:41:30
User entered 'Does not interfere with activity (2)'	System	12 Aug 2020 19:41:30

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:41:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-12T12:41:15', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '63d025dd-e862-40f6-9e45-fde1552c7d03'	System	12 Aug 2020 19:41:30
User entered 'No (N)'	System	12 Aug 2020 19:41:30



US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:41:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-12T12:41:18', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '63d025dd-e862-40f6-9e45-fde1552c7d03'	System	12 Aug 2020 19:41:30
User entered 'Yes (Y)'	System	12 Aug 2020 19:41:30

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:41:32

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-12T12:41:21', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '63d025dd-e862-40f6-9e45-fde1552c7d03'	System	12 Aug 2020 19:41:30
User entered '4'	System	12 Aug 2020 19:41:30

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:41:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-12T12:41:25', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '63d025dd-e862-40f6-9e45-fde1552c7d03'	System	12 Aug 2020 19:41:30
User entered 'None (1)'	System	12 Aug 2020 19:41:30

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:41:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-12T12:41:27', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '63d025dd-e862-40f6-9e45-fde1552c7d03'	System	12 Aug 2020 19:41:30
User entered '12 Aug 2020 12:41'	System	12 Aug 2020 19:41:30

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:41:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:41:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
Data entry locked.	System	11 Aug 2020 19:31:39
User entered 'Day 3'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:41:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-13T12:08:37', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '1c2b2eec-3a53-4d83-82dd-86d7d6a712a9'	System	13 Aug 2020 19:08:53
User entered 'None (1)'	System	13 Aug 2020 19:08:53



US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:41:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-13T12:08:40', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '1c2b2eec-3a53-4d83-82dd-86d7d6a712a9'	System	13 Aug 2020 19:08:53
User entered 'No (N)'	System	13 Aug 2020 19:08:53

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:41:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-13T12:08:43', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '1c2b2eec-3a53-4d83-82dd-86d7d6a712a9'	System	13 Aug 2020 19:08:53
User entered 'Yes (Y)'	System	13 Aug 2020 19:08:53

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:41:32

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-13T12:08:46', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '1c2b2eec-3a53-4d83-82dd-86d7d6a712a9'	System	13 Aug 2020 19:08:53
User entered '3'	System	13 Aug 2020 19:08:53

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:41:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-13T12:08:49', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '1c2b2eec-3a53-4d83-82dd-86d7d6a712a9'	System	13 Aug 2020 19:08:53
User entered 'None (1)'	System	13 Aug 2020 19:08:53

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:41:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-13T12:08:51', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '1c2b2eec-3a53-4d83-82dd-86d7d6a712a9'	System	13 Aug 2020 19:08:53
User entered '13 Aug 2020 12:08'	System	13 Aug 2020 19:08:53

**US3462116**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:41:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:41:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
Data entry locked.	System	11 Aug 2020 19:31:39
User entered 'Day 4'	System	11 Aug 2020 19:31:39



US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:41:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-14T14:59:54', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '252a7445-17a3-463c-ad8b-35f0f14e5d06'	System	14 Aug 2020 22:00:10
User entered 'None (1)'	System	14 Aug 2020 22:00:10

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:41:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-14T14:59:57', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '252a7445-17a3-463c-ad8b-35f0f14e5d06'	System	14 Aug 2020 22:00:10
User entered 'No (N)'	System	14 Aug 2020 22:00:10

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:41:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-14T15:00:00', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '252a7445-17a3-463c-ad8b-35f0f14e5d06'	System	14 Aug 2020 22:00:10
User entered 'No (N)'	System	14 Aug 2020 22:00:10

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:41:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-14T15:00:02', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '252a7445-17a3-463c-ad8b-35f0f14e5d06'	System	14 Aug 2020 22:00:10
User entered 'None (1)'	System	14 Aug 2020 22:00:10

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:41:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-14T15:00:04', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '252a7445-17a3-463c-ad8b-35f0f14e5d06'	System	14 Aug 2020 22:00:10
User entered '14 Aug 2020 15:00'	System	14 Aug 2020 22:00:10

**US3462116**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 17:41:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:41:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 19:31:39

**US3462116**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
Data entry locked.	System	11 Aug 2020 19:31:39
User entered 'Day 5'	System	11 Aug 2020 19:31:39



US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:41:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-15T12:00:52', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'bc67f1ec-9900-4237-8e93-0b918f8f773f'	System	15 Aug 2020 19:01:07
User entered 'None (1)'	System	15 Aug 2020 19:01:07

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:41:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-15T12:00:54', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'bc67f1ec-9900-4237-8e93-0b918f8f773f'	System	15 Aug 2020 19:01:07
User entered 'No (N)'	System	15 Aug 2020 19:01:07

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:41:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-15T12:00:57', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'bc67f1ec-9900-4237-8e93-0b918f8f773f'	System	15 Aug 2020 19:01:07
User entered 'No (N)'	System	15 Aug 2020 19:01:07

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:41:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-15T12:00:59', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'bc67f1ec-9900-4237-8e93-0b918f8f773f'	System	15 Aug 2020 19:01:07
User entered 'None (1)'	System	15 Aug 2020 19:01:07

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:41:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-15T12:01:01', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'bc67f1ec-9900-4237-8e93-0b918f8f773f'	System	15 Aug 2020 19:01:07
User entered '15 Aug 2020 12:01'	System	15 Aug 2020 19:01:07

**US3462116**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:41:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 19:31:39

**US3462116**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:41:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
Data entry locked.	System	11 Aug 2020 19:31:39
User entered 'Day 6'	System	11 Aug 2020 19:31:39



US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:41:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-16T14:51:11', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '94aa7600-6e65-4f3e-9933-aa926ae9676d'	System	16 Aug 2020 21:51:23
User entered 'None (1)'	System	16 Aug 2020 21:51:23

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:41:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-16T14:51:13', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '94aa7600-6e65-4f3e-9933-aa926ae9676d'	System	16 Aug 2020 21:51:23
User entered 'No (N)'	System	16 Aug 2020 21:51:23

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:41:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-16T14:51:14', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '94aa7600-6e65-4f3e-9933-aa926ae9676d'	System	16 Aug 2020 21:51:23
User entered 'No (N)'	System	16 Aug 2020 21:51:23

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:41:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-16T14:51:16', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '94aa7600-6e65-4f3e-9933-aa926ae9676d'	System	16 Aug 2020 21:51:23
User entered 'None (1)'	System	16 Aug 2020 21:51:23

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:41:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-16T14:51:20', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '94aa7600-6e65-4f3e-9933-aa926ae9676d'	System	16 Aug 2020 21:51:23
User entered '16 Aug 2020 14:51'	System	16 Aug 2020 21:51:23

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:41:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:41:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
Data entry locked.	System	11 Aug 2020 19:31:39
User entered 'Day 7'	System	11 Aug 2020 19:31:39



US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:41:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-17T12:18:14', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '1215a8ae-c2cb-4812-84c2-75b2051adc3d'	System	17 Aug 2020 19:18:27
User entered 'None (1)'	System	17 Aug 2020 19:18:27

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:41:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-17T12:18:17', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '1215a8ae-c2cb-4812-84c2-75b2051adc3d'	System	17 Aug 2020 19:18:27
User entered 'No (N)'	System	17 Aug 2020 19:18:27

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:41:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-17T12:18:18', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '1215a8ae-c2cb-4812-84c2-75b2051adc3d'	System	17 Aug 2020 19:18:27
User entered 'No (N)'	System	17 Aug 2020 19:18:27

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:41:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-17T12:18:20', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '1215a8ae-c2cb-4812-84c2-75b2051adc3d'	System	17 Aug 2020 19:18:27
User entered 'None (1)'	System	17 Aug 2020 19:18:27

US3462116

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:41:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-17T12:18:22', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '1215a8ae-c2cb-4812-84c2-75b2051adc3d'	System	17 Aug 2020 19:18:27
User entered '17 Aug 2020 12:18'	System	17 Aug 2020 19:18:27

**US3462116**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:41:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 19:31:39

**US3462116**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:41:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
Data entry locked.	System	11 Aug 2020 19:31:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 19:31:39



US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:41:32

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-11T12:56:44', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '83698c16-d44d-40d0-bdb9-01dca5eafe73'	System	11 Aug 2020 19:57:13
User entered 'None (0)'	System	11 Aug 2020 19:57:13

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:41:32

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-11T12:56:47', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '83698c16-d44d-40d0-bdb9-01dca5eafe73'	System	11 Aug 2020 19:57:13
User entered 'None (0)'	System	11 Aug 2020 19:57:13

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:41:32

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-11T12:56:50', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '83698c16-d44d-40d0-bdb9-01dca5eafe73'	System	11 Aug 2020 19:57:13
User entered 'None (0)'	System	11 Aug 2020 19:57:13

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:41:32

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-11T12:56:52', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '83698c16-d44d-40d0-bdb9-01dca5eafe73'	System	11 Aug 2020 19:57:13
User entered 'None (0)'	System	11 Aug 2020 19:57:13

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:41:32

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-11T12:56:55', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '83698c16-d44d-40d0-bdb9-01dca5eafe73'	System	11 Aug 2020 19:57:13
User entered 'None (0)'	System	11 Aug 2020 19:57:13

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:41:32

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-11T12:56:58', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '83698c16-d44d-40d0-bdb9-01dca5eafe73'	System	11 Aug 2020 19:57:13
User entered 'None (0)'	System	11 Aug 2020 19:57:13

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:41:32

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)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-11T12:57:05', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '83698c16-d44d-40d0-bdb9-01dca5eafe73'	System	11 Aug 2020 19:57:13
User entered 'No (N)'	System	11 Aug 2020 19:57:13

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:41:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-11T12:57:08', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '83698c16-d44d-40d0-bdb9-01dca5eafe73'	System	11 Aug 2020 19:57:13
User entered '11 Aug 2020 12:57'	System	11 Aug 2020 19:57:13



**US3462116**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:41:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '11 Aug 2020 12:42'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:41:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '11 Aug 2020 15:12'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
Data entry locked.	System	11 Aug 2020 19:31:39
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:41:32

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-11T16:12:18', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '9d17371d-716a-4176-b574-9444bc6a9bde'	System	11 Aug 2020 23:12:42
User entered 'None (0)'	System	11 Aug 2020 23:12:42

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:41:32

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-11T16:12:20', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '9d17371d-716a-4176-b574-9444bc6a9bde'	System	11 Aug 2020 23:12:42
User entered 'None (0)'	System	11 Aug 2020 23:12:42

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:41:32

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-11T16:12:22', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '9d17371d-716a-4176-b574-9444bc6a9bde'	System	11 Aug 2020 23:12:42
User entered 'None (0)'	System	11 Aug 2020 23:12:42

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:41:32

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-11T16:12:25', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '9d17371d-716a-4176-b574-9444bc6a9bde'	System	11 Aug 2020 23:12:42
User entered 'None (0)'	System	11 Aug 2020 23:12:42

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:41:32

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-11T16:12:27', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '9d17371d-716a-4176-b574-9444bc6a9bde'	System	11 Aug 2020 23:12:42
User entered 'None (0)'	System	11 Aug 2020 23:12:42



US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:41:32

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-11T16:12:29', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '9d17371d-716a-4176-b574-9444bc6a9bde'	System	11 Aug 2020 23:12:42
User entered 'None (0)'	System	11 Aug 2020 23:12:42

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:41:32

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)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-11T16:12:33', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '9d17371d-716a-4176-b574-9444bc6a9bde'	System	11 Aug 2020 23:12:42
User entered 'No (N)'	System	11 Aug 2020 23:12:42

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:41:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-11T16:12:40', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '9d17371d-716a-4176-b574-9444bc6a9bde'	System	11 Aug 2020 23:12:42
User entered '11 Aug 2020 16:12'	System	11 Aug 2020 23:12:42

**US3462116**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:41:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '11 Aug 2020 16:07'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:41:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
Data entry locked.	System	11 Aug 2020 19:31:39
User entered 'Day 2'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:41:32

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-12T12:41:31', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '4298c30f-0945-49e5-8feb-d418a97174d5'	System	12 Aug 2020 19:41:52
User entered 'None (0)'	System	12 Aug 2020 19:41:52

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:41:32

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-12T12:41:33', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '4298c30f-0945-49e5-8feb-d418a97174d5'	System	12 Aug 2020 19:41:52
User entered 'None (0)'	System	12 Aug 2020 19:41:52



US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:41:32

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-12T12:41:36', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '4298c30f-0945-49e5-8feb-d418a97174d5'	System	12 Aug 2020 19:41:52
User entered 'None (0)'	System	12 Aug 2020 19:41:52

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:41:32

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-12T12:41:38', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '4298c30f-0945-49e5-8feb-d418a97174d5'	System	12 Aug 2020 19:41:52
User entered 'None (0)'	System	12 Aug 2020 19:41:52

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:41:32

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-12T12:41:41', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '4298c30f-0945-49e5-8feb-d418a97174d5'	System	12 Aug 2020 19:41:52
User entered 'None (0)'	System	12 Aug 2020 19:41:52

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:41:32

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-12T12:41:43', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '4298c30f-0945-49e5-8feb-d418a97174d5'	System	12 Aug 2020 19:41:52
User entered 'None (0)'	System	12 Aug 2020 19:41:52

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:41:32

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)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-12T12:41:46', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '4298c30f-0945-49e5-8feb-d418a97174d5'	System	12 Aug 2020 19:41:52
User entered 'No (N)'	System	12 Aug 2020 19:41:52

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:41:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-12T12:41:49', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '4298c30f-0945-49e5-8feb-d418a97174d5'	System	12 Aug 2020 19:41:52
User entered '12 Aug 2020 12:41'	System	12 Aug 2020 19:41:52

**US3462116**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:41:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:41:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 19:31:39



US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
Data entry locked.	System	11 Aug 2020 19:31:39
User entered 'Day 3'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:41:32

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-13T12:08:55', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '2a183abe-3b58-4f02-9dc4-cd8a3c6686c0'	System	13 Aug 2020 19:09:13
User entered 'None (0)'	System	13 Aug 2020 19:09:13

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:41:32

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-13T12:08:57', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '2a183abe-3b58-4f02-9dc4-cd8a3c6686c0'	System	13 Aug 2020 19:09:13
User entered 'None (0)'	System	13 Aug 2020 19:09:13

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:41:32

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-13T12:08:58', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '2a183abe-3b58-4f02-9dc4-cd8a3c6686c0'	System	13 Aug 2020 19:09:13
User entered 'None (0)'	System	13 Aug 2020 19:09:13

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:41:32

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-13T12:09:00', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '2a183abe-3b58-4f02-9dc4-cd8a3c6686c0'	System	13 Aug 2020 19:09:13
User entered 'None (0)'	System	13 Aug 2020 19:09:13

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:41:32

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-13T12:09:02', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '2a183abe-3b58-4f02-9dc4-cd8a3c6686c0'	System	13 Aug 2020 19:09:13
User entered 'None (0)'	System	13 Aug 2020 19:09:13

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:41:32

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-13T12:09:05', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '2a183abe-3b58-4f02-9dc4-cd8a3c6686c0'	System	13 Aug 2020 19:09:13
User entered 'None (0)'	System	13 Aug 2020 19:09:13

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:41:32

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)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-13T12:09:07', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '2a183abe-3b58-4f02-9dc4-cd8a3c6686c0'	System	13 Aug 2020 19:09:13
User entered 'No (N)'	System	13 Aug 2020 19:09:13



US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:41:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-13T12:09:09', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '2a183abe-3b58-4f02-9dc4-cd8a3c6686c0'	System	13 Aug 2020 19:09:13
User entered '13 Aug 2020 12:09'	System	13 Aug 2020 19:09:13

**US3462116**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:41:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 19:31:39

**US3462116**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:41:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
Data entry locked.	System	11 Aug 2020 19:31:39
User entered 'Day 4'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:41:32

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-14T15:00:08', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'f5b20499-7cee-4670-92ac-52ef283888ac'	System	14 Aug 2020 22:00:23
User entered 'None (0)'	System	14 Aug 2020 22:00:23

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:41:32

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-14T15:00:10', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'f5b20499-7cee-4670-92ac-52ef283888ac'	System	14 Aug 2020 22:00:23
User entered 'None (0)'	System	14 Aug 2020 22:00:23

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:41:32

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-14T15:00:11', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'f5b20499-7cee-4670-92ac-52ef283888ac'	System	14 Aug 2020 22:00:23
User entered 'None (0)'	System	14 Aug 2020 22:00:23

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:41:32

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-14T15:00:13', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'f5b20499-7cee-4670-92ac-52ef283888ac'	System	14 Aug 2020 22:00:23
User entered 'None (0)'	System	14 Aug 2020 22:00:23



US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:41:32

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-14T15:00:14', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'f5b20499-7cee-4670-92ac-52ef283888ac'	System	14 Aug 2020 22:00:23
User entered 'None (0)'	System	14 Aug 2020 22:00:23

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:41:32

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-14T15:00:16', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'f5b20499-7cee-4670-92ac-52ef283888ac'	System	14 Aug 2020 22:00:23
User entered 'None (0)'	System	14 Aug 2020 22:00:23

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:41:32

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)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-14T15:00:18', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'f5b20499-7cee-4670-92ac-52ef283888ac'	System	14 Aug 2020 22:00:23
User entered 'No (N)'	System	14 Aug 2020 22:00:23

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:41:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-14T15:00:20', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'f5b20499-7cee-4670-92ac-52ef283888ac'	System	14 Aug 2020 22:00:23
User entered '14 Aug 2020 15:00'	System	14 Aug 2020 22:00:23

**US3462116**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:41:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 19:31:39

**US3462116**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:41:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
Data entry locked.	System	11 Aug 2020 19:31:39
User entered 'Day 5'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:41:32

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-15T12:01:06', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'dbc97009-77dd-4846-ac1b-17a63ebd8297'	System	15 Aug 2020 19:01:25
User entered 'None (0)'	System	15 Aug 2020 19:01:25



US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:41:32

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-15T12:01:08', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'dbc97009-77dd-4846-ac1b-17a63ebd8297'	System	15 Aug 2020 19:01:25
User entered 'None (0)'	System	15 Aug 2020 19:01:25

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:41:32

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-15T12:01:10', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'dbc97009-77dd-4846-ac1b-17a63ebd8297'	System	15 Aug 2020 19:01:25
User entered 'None (0)'	System	15 Aug 2020 19:01:25

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:41:32

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-15T12:01:11', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'dbc97009-77dd-4846-ac1b-17a63ebd8297'	System	15 Aug 2020 19:01:25
User entered 'None (0)'	System	15 Aug 2020 19:01:25

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:41:32

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-15T12:01:13', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'dbc97009-77dd-4846-ac1b-17a63ebd8297'		15 Aug 2020 19:01:25
User entered 'None (0)'	System	15 Aug 2020 19:01:25

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:41:32

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-15T12:01:15', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'dbc97009-77dd-4846-ac1b-17a63ebd8297'	System	15 Aug 2020 19:01:25
User entered 'None (0)'	System	15 Aug 2020 19:01:25

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:41:32

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)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-15T12:01:18', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'dbc97009-77dd-4846-ac1b-17a63ebd8297'	System	15 Aug 2020 19:01:25
User entered 'No (N)'	System	15 Aug 2020 19:01:25

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:41:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-15T12:01:20', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'dbc97009-77dd-4846-ac1b-17a63ebd8297'	System	15 Aug 2020 19:01:25
User entered '15 Aug 2020 12:01'	System	15 Aug 2020 19:01:25

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:41:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 19:31:39



**US3462116**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:41:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
Data entry locked.	System	11 Aug 2020 19:31:39
User entered 'Day 6'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:41:32

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-16T14:51:23', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '9ce1fe09-5250-489f-856a-5eee48337259'	System	16 Aug 2020 21:51:37
User entered 'None (0)'	System	16 Aug 2020 21:51:37

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:41:32

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-16T14:51:25', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '9ce1fe09-5250-489f-856a-5eee48337259'	System	16 Aug 2020 21:51:37
User entered 'None (0)'	System	16 Aug 2020 21:51:37

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:41:32

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-16T14:51:26', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '9ce1fe09-5250-489f-856a-5eee48337259'	System	16 Aug 2020 21:51:37
User entered 'None (0)'	System	16 Aug 2020 21:51:37

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:41:32

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-16T14:51:28', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '9ce1fe09-5250-489f-856a-5eee48337259'	System	16 Aug 2020 21:51:37
User entered 'None (0)'	System	16 Aug 2020 21:51:37

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:41:32

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-16T14:51:29', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '9ce1fe09-5250-489f-856a-5eee48337259'	System	16 Aug 2020 21:51:37
User entered 'None (0)'	System	16 Aug 2020 21:51:37

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:41:32

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-16T14:51:31', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '9ce1fe09-5250-489f-856a-5eee48337259'	System	16 Aug 2020 21:51:37
User entered 'None (0)'	System	16 Aug 2020 21:51:37



US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:41:32

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)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-16T14:51:33', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '9ce1fe09-5250-489f-856a-5eee48337259'	System	16 Aug 2020 21:51:37
User entered 'No (N)'	System	16 Aug 2020 21:51:37

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:41:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-16T14:51:35', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '9ce1fe09-5250-489f-856a-5eee48337259'	System	16 Aug 2020 21:51:37
User entered '16 Aug 2020 14:51'	System	16 Aug 2020 21:51:37

**US3462116**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:41:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 19:31:39

**US3462116**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:41:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 19:31:39

**US3462116**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
Data entry locked.	System	11 Aug 2020 19:31:39
User entered 'Day 7'	System	11 Aug 2020 19:31:39

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:41:32

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-17T12:18:26', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '420c6016-e233-4a20-9ccd-33673cf094cc'	System	17 Aug 2020 19:18:42
User entered 'None (0)'	System	17 Aug 2020 19:18:42

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:41:32

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-17T12:18:28', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '420c6016-e233-4a20-9ccd-33673cf094cc'	System	17 Aug 2020 19:18:42
User entered 'None (0)'	System	17 Aug 2020 19:18:42

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:41:32

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-17T12:18:29', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '420c6016-e233-4a20-9ccd-33673cf094cc'	System	17 Aug 2020 19:18:42
User entered 'None (0)'	System	17 Aug 2020 19:18:42



US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:41:32

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-17T12:18:31', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '420c6016-e233-4a20-9ccd-33673cf094cc'	System	17 Aug 2020 19:18:42
User entered 'None (0)'	System	17 Aug 2020 19:18:42

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:41:32

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-17T12:18:33', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '420c6016-e233-4a20-9ccd-33673cf094cc'	System	17 Aug 2020 19:18:42
User entered 'None (0)'	System	17 Aug 2020 19:18:42

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:41:32

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-17T12:18:34', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '420c6016-e233-4a20-9ccd-33673cf094cc'	System	17 Aug 2020 19:18:42
User entered 'None (0)'	System	17 Aug 2020 19:18:42

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:41:32

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)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-17T12:18:36', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '420c6016-e233-4a20-9ccd-33673cf094cc'	System	17 Aug 2020 19:18:42
User entered 'No (N)'	System	17 Aug 2020 19:18:42

US3462116

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:41:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-08-17T12:18:38', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '420c6016-e233-4a20-9ccd-33673cf094cc'	System	17 Aug 2020 19:18:42
User entered '17 Aug 2020 12:18'	System	17 Aug 2020 19:18:42

**US3462116**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:41:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 19:31:39

**US3462116**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:41:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 19:31:39

US3462116

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	08 Sep 2020 16:14:37



US3462116

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:32

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User closed query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	08 Sep 2020 16:15:14
Query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	08 Sep 2020 16:15:14
User entered '18 Aug 2020' reason for change: Data Entry Error	Danuel Hamlin (b) (4)	08 Sep 2020 16:15:14
User opened query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	08 Sep 2020 16:14:37
User entered '25 Aug 2020'	Danuel Hamlin (b) (4)	08 Sep 2020 16:14:37

US3462116

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danuel Hamlin (b) (4)	08 Sep 2020 16:14:37

US3462116

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:32

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	08 Sep 2020 16:14:37

US3462116

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	08 Sep 2020 16:15:23

**US3462116**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:41:32**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User entered 'I'	System	08 Sep 2020 16:15:23

**US3462116**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:41:32**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	08 Sep 2020 16:15:51

**US3462116**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:41:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '25 Aug 2020'	(b) (4) Danuel Hamlin (b) (4)	08 Sep 2020 16:15:51

US3462116

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danuel Hamlin (b) (4)	08 Sep 2020 16:15:51



US3462116

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:32

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	08 Sep 2020 16:15:51

US3462116

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	08 Sep 2020 16:16:08

**US3462116**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:41:32**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User entered 'I'	System	08 Sep 2020 16:16:08

**US3462116**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:41:32**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	08 Sep 2020 16:17:54

US3462116

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '01 Sep 2020'	(b) (4) Danuel Hamlin (b) (4)	08 Sep 2020 16:17:54

**US3462116**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:41:32**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danuel Hamlin (b) (4)	08 Sep 2020 16:17:54

US3462116

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:32

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	08 Sep 2020 16:17:54

US3462116

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	08 Sep 2020 16:18:04



**US3462116**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:41:32**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User entered 'I'	System	08 Sep 2020 16:18:04

US3462116

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:41:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 13OCT2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Nov 2020 02:33:14
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 13OCT2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'Added' (Site from DM).	Danuel Hamlin (b) (4)	09 Nov 2020 08:42:36
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 13OCT2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 08:29:12
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	14 Sep 2020 21:15:06

US3462116

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:41:32

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '14 Sep 2020'	(b) (4) Danuel Hamlin (b) (4)	14 Sep 2020 21:15:06

US3462116

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:41:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'Clinic (Clinic)'	(b) (4) Danuel Hamlin (b) (4)	14 Sep 2020 21:15:06

**US3462116**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:41:32**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User entered 'VISIT2'	System	14 Sep 2020 21:15:06

US3462116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:32

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User accepted default value 'Pre-Dose (PREDOSE)'	Danuel Hamlin (b) (4)	14 Sep 2020 21:15:42

US3462116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	14 Sep 2020 21:15:42

US3462116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '14 Sep 2020'	(b) (4) Danuel Hamlin (b) (4)	14 Sep 2020 21:15:42



US3462116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '13:26'	(b) (4) Danuel Hamlin (b) (4)	14 Sep 2020 21:15:42

US3462116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:32

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User entered '14 Sep 2020 13:26'	System	14 Sep 2020 21:15:42

US3462116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '97.3' F	(b) (4) Danuel Hamlin (b) (4)	14 Sep 2020 21:15:42

US3462116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'Other (Other)'	(b) (4) Danuel Hamlin (b) (4)	14 Sep 2020 21:15:42

US3462116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'Tympanic'	(b) (4) Danuel Hamlin (b) (4)	14 Sep 2020 21:15:42

US3462116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '70'	(b) (4) Danuel Hamlin (b) (4)	14 Sep 2020 21:15:42

**US3462116**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:41:32**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User entered 'bpm'	System	14 Sep 2020 21:15:42

US3462116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:32

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '16'	(b) (4) Danuel Hamlin (b) (4)	14 Sep 2020 21:15:42



US3462116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User entered 'breaths/min'	System	14 Sep 2020 21:15:42

US3462116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '122'	(b) (4) Danuel Hamlin (b) (4)	14 Sep 2020 21:15:42

US3462116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User entered 'mmHg'	System	14 Sep 2020 21:15:42

US3462116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '70'	(b) (4) Danuel Hamlin (b) (4)	14 Sep 2020 21:15:42

US3462116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:32

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User entered 'mmHg'	System	14 Sep 2020 21:15:42

US3462116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:32

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User accepted default value 'Post-Dose (POSTDOSE)'	Danuel Hamlin (b) (4)	04 Nov 2020 14:35:12

US3462116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 14:35:12

US3462116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '14 Sep 2020'	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 14:35:12



US3462116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '14:21'	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 14:35:12

**US3462116**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:41:32**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User entered '14 Sep 2020 14:21'	System	04 Nov 2020 14:35:12

US3462116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '97.5' F	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 14:35:12

US3462116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'Other (Other)'	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 14:35:12

US3462116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'Tympanic'	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 14:35:12

US3462116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '88'	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 14:35:12

**US3462116**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:41:32**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User entered 'bpm'	System	04 Nov 2020 14:35:12

US3462116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:32

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '14'	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 14:35:12



US3462116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User entered 'breaths/min'	System	04 Nov 2020 14:35:12

US3462116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '120'	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 14:35:12

US3462116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User entered 'mmHg'	System	04 Nov 2020 14:35:12

US3462116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '70'	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 14:35:12

US3462116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:32

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User entered 'mmHg'	System	04 Nov 2020 14:35:12

US3462116

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:41:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	14 Sep 2020 21:15:53

US3462116

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:41:32

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '14 Sep 2020'	(b) (4) Danuel Hamlin (b) (4)	14 Sep 2020 21:15:53

US3462116

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:41:32

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	14 Sep 2020 21:16:23



US3462116

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:41:32

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	14 Sep 2020 21:16:23

US3462116

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:41:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered empty.	Danuel Hamlin (b) (4)	14 Sep 2020 21:16:23

US3462116

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:41:32

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User entered 'MRNA-1273 OR PLACEBO'	System	14 Sep 2020 21:16:23

US3462116

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:41:32

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '14 Sep 2020'	(b) (4) Danuel Hamlin (b) (4)	14 Sep 2020 21:16:23

US3462116

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:41:32

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '13:50'	(b) (4) Danuel Hamlin (b) (4)	14 Sep 2020 21:16:23

US3462116

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:41:32

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User entered '14 Sep 2020 13:50'	System	14 Sep 2020 21:16:23

US3462116

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:41:32

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
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) (4), (b) (6)	13 Nov 2020 15:11:38
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 'IP was administered in Right Arm at both visits. ' (Site from System).	Danuel Hamlin (b) (4)	10 Nov 2020 02:33:54
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	14 Sep 2020 21:16:23
User entered 'Right Arm (RIGHT ARM)'	Danuel Hamlin (b) (4)	14 Sep 2020 21:16:23

US3462116

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:41:32

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User entered 'ONCE'	System	14 Sep 2020 21:16:23



US3462116

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:41:32

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User entered 'INTRAMUSCULAR'	System	14 Sep 2020 21:16:23

US3462116

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	14 Sep 2020 21:17:30

US3462116

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:32

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '14 Sep 2020'	(b) (4) Danuel Hamlin (b) (4)	14 Sep 2020 21:17:30

US3462116

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:32

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '13:41'	(b) (4) Danuel Hamlin (b) (4)	14 Sep 2020 21:17:30

**US3462116**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:41:32**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User entered '14 Sep 2020 13:41'	System	14 Sep 2020 21:17:30

US3462116

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:41:32

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '14 Sep 2020'	(b) (4) Danuel Hamlin (b) (4)	14 Sep 2020 21:17:53

**US3462116**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:41:32**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Danuel Hamlin (b) (4)	14 Sep 2020 21:17:53

US3462116

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:41:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	14 Sep 2020 21:17:53



US3462116

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:41:32

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '13:43'	(b) (4) Danuel Hamlin (b) (4)	14 Sep 2020 21:17:53

**US3462116**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:41:32**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User entered '14 Sep 2020 13:43'	System	14 Sep 2020 21:17:53

US3462116

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:41:32

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Danuel Hamlin (b) (4)	14 Sep 2020 21:17:53

US3462116

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:41:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	09 Oct 2020 20:34:53
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	14 Sep 2020 21:17:53

US3462116

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:41:32

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	09 Oct 2020 20:34:53
User entered '13:43'	Danuel Hamlin (b) (4)	14 Sep 2020 21:17:53

**US3462116**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:41:32**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User entered empty.	System	09 Oct 2020 20:34:53
User entered '14 Sep 2020 13:43'	System	14 Sep 2020 21:17:53

US3462116

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	14 Sep 2020 21:18:00

**US3462116**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:41:32**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User entered 'I'	System	14 Sep 2020 21:18:00



US3462116

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
Data entry locked.	System	14 Sep 2020 21:16:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:41:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-14T14:19:41', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'b0e8b846-6288-4f97-a180-740e76c8b909'	System	14 Sep 2020 21:20:14
User entered 'Yes (Y)'	System	14 Sep 2020 21:20:14

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:41:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-14T14:19:53', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'b0e8b846-6288-4f97-a180-740e76c8b909'	System	14 Sep 2020 21:20:14
User entered '97.6'	System	14 Sep 2020 21:20:14

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:41:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-14T14:19:56', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'b0e8b846-6288-4f97-a180-740e76c8b909'	System	14 Sep 2020 21:20:14
User entered 'No (N)'	System	14 Sep 2020 21:20:14

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:41:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-14T14:20:09', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'b0e8b846-6288-4f97-a180-740e76c8b909'	System	14 Sep 2020 21:20:14
User entered '14 Sep 2020 14:20'	System	14 Sep 2020 21:20:14

**US3462116**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 17:41:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '14 Sep 2020 14:10'	System	14 Sep 2020 21:16:23

**US3462116**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 17:41:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '14 Sep 2020 16:40'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
Data entry locked.	System	14 Sep 2020 21:16:23
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 21:16:23



US3462116

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:41:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-14T17:39:46', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '5953f1e7-dc00-4b06-a9d3-0bf12260890e'	System	15 Sep 2020 00:40:11
User entered 'Yes (Y)'	System	15 Sep 2020 00:40:11

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:41:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-14T17:40:01', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '5953f1e7-dc00-4b06-a9d3-0bf12260890e'	System	15 Sep 2020 00:40:11
User entered '97.0'	System	15 Sep 2020 00:40:11

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:41:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-14T17:40:03', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '5953f1e7-dc00-4b06-a9d3-0bf12260890e'	System	15 Sep 2020 00:40:11
User entered 'No (N)'	System	15 Sep 2020 00:40:11

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:41:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-14T17:40:06', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '5953f1e7-dc00-4b06-a9d3-0bf12260890e'	System	15 Sep 2020 00:40:11
User entered '14 Sep 2020 17:40'	System	15 Sep 2020 00:40:11

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:41:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '14 Sep 2020 17:35'	System	14 Sep 2020 21:16:23

**US3462116**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 17:41:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
Data entry locked.	System	14 Sep 2020 21:16:23
User entered 'Day 2'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:41:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27



US3462116

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:41:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:41:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:41:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:41:32

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27

**US3462116**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 17:41:32**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:41:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 21:16:23

**US3462116**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 17:41:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
Data entry locked.	System	14 Sep 2020 21:16:23
User entered 'Day 3'	System	14 Sep 2020 21:16:23



US3462116

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:41:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-16T17:37:43', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '40571f9d-1b96-4dfa-870f-a5a4eafc1558'	System	17 Sep 2020 00:37:57
User entered 'Yes (Y)'	System	17 Sep 2020 00:37:57

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:41:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-16T17:37:47', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '40571f9d-1b96-4dfa-870f-a5a4eafc1558'	System	17 Sep 2020 00:37:57
User entered '97.5'	System	17 Sep 2020 00:37:57

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:41:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-16T17:37:50', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '40571f9d-1b96-4dfa-870f-a5a4eafc1558'	System	17 Sep 2020 00:37:57
User entered 'No (N)'	System	17 Sep 2020 00:37:57

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:41:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-16T17:37:53', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '40571f9d-1b96-4dfa-870f-a5a4eafc1558'	System	17 Sep 2020 00:37:57
User entered '16 Sep 2020 17:37'	System	17 Sep 2020 00:37:57

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:41:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:41:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
Data entry locked.	System	14 Sep 2020 21:16:23
User entered 'Day 4'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:41:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-17T12:18:28', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'd931564d-77a9-4600-92bd-ffdf44da8c36'	System	17 Sep 2020 19:18:44
User entered 'Yes (Y)'	System	17 Sep 2020 19:18:44



US3462116

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:41:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-17T12:18:32', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'd931564d-77a9-4600-92bd-ffdf44da8c36'	System	17 Sep 2020 19:18:44
User entered '97.8'	System	17 Sep 2020 19:18:44

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:41:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-17T12:18:36', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'd931564d-77a9-4600-92bd-ffdf44da8c36'	System	17 Sep 2020 19:18:44
User entered 'No (N)'	System	17 Sep 2020 19:18:44

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:41:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-17T12:18:38', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'd931564d-77a9-4600-92bd-ffdf44da8c36'	System	17 Sep 2020 19:18:44
User entered '17 Sep 2020 12:18'	System	17 Sep 2020 19:18:44

**US3462116**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 17:41:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 21:16:23

**US3462116**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 17:41:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
Data entry locked.	System	14 Sep 2020 21:16:23
User entered 'Day 5'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:41:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-18T14:48:16', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '36941127-2008-4693-a40f-67940f942168'	System	18 Sep 2020 21:48:32
User entered 'Yes (Y)'	System	18 Sep 2020 21:48:32

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:41:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-18T14:48:21', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '36941127-2008-4693-a40f-67940f942168'	System	18 Sep 2020 21:48:32
User entered '97.0'	System	18 Sep 2020 21:48:32



US3462116

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:41:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-18T14:48:23', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '36941127-2008-4693-a40f-67940f942168'	System	18 Sep 2020 21:48:32
User entered 'No (N)'	System	18 Sep 2020 21:48:32

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:41:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-18T14:48:26', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '36941127-2008-4693-a40f-67940f942168'	System	18 Sep 2020 21:48:32
User entered '18 Sep 2020 14:48'	System	18 Sep 2020 21:48:32

**US3462116**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 17:41:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:41:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
Data entry locked.	System	14 Sep 2020 21:16:23
User entered 'Day 6'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:41:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-19T12:01:51', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '2bc18dd5-ae11-430f-9a8b-919d8b1d8f94'	System	19 Sep 2020 19:02:07
User entered 'Yes (Y)'	System	19 Sep 2020 19:02:07

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:41:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-19T12:01:58', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '2bc18dd5-ae11-430f-9a8b-919d8b1d8f94'	System	19 Sep 2020 19:02:07
User entered '97.8'	System	19 Sep 2020 19:02:07

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:41:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-19T12:02:01', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '2bc18dd5-ae11-430f-9a8b-919d8b1d8f94'	System	19 Sep 2020 19:02:07
User entered 'No (N)'	System	19 Sep 2020 19:02:07



US3462116

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:41:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-19T12:02:04', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '2bc18dd5-ae11-430f-9a8b-919d8b1d8f94'	System	19 Sep 2020 19:02:07
User entered '19 Sep 2020 12:02'	System	19 Sep 2020 19:02:07

**US3462116**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 17:41:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 21:16:23

**US3462116**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 17:41:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
Data entry locked.	System	14 Sep 2020 21:16:23
User entered 'Day 7'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:41:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-20T17:14:01', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'fc881263-6e6a-4240-ba93-392b353de396'	System	21 Sep 2020 00:14:18
User entered 'Yes (Y)'	System	21 Sep 2020 00:14:18

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:41:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-20T17:14:05', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'fc881263-6e6a-4240-ba93-392b353de396'	System	21 Sep 2020 00:14:18
User entered '98.0'	System	21 Sep 2020 00:14:18

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:41:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-20T17:14:08', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'fc881263-6e6a-4240-ba93-392b353de396'	System	21 Sep 2020 00:14:18
User entered 'No (N)'	System	21 Sep 2020 00:14:18

US3462116

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:41:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-20T17:14:12', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'fc881263-6e6a-4240-ba93-392b353de396'	System	21 Sep 2020 00:14:18
User entered '20 Sep 2020 17:14'	System	21 Sep 2020 00:14:18



US3462116

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:41:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 21:16:23

**US3462116**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 17:41:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
Data entry locked.	System	14 Sep 2020 21:16:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:41:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-14T14:20:14', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'eda360d9-8a9b-4c76-9de0-3f5da48538d9'	System	14 Sep 2020 21:20:28
User entered 'None (1)'	System	14 Sep 2020 21:20:28

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:41:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-14T14:20:17', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'eda360d9-8a9b-4c76-9de0-3f5da48538d9'	System	14 Sep 2020 21:20:28
User entered 'No (N)'	System	14 Sep 2020 21:20:28

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:41:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-14T14:20:19', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'eda360d9-8a9b-4c76-9de0-3f5da48538d9'	System	14 Sep 2020 21:20:28
User entered 'No (N)'	System	14 Sep 2020 21:20:28

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:41:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-14T14:20:21', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'eda360d9-8a9b-4c76-9de0-3f5da48538d9'	System	14 Sep 2020 21:20:28
User entered 'None (1)'	System	14 Sep 2020 21:20:28

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:41:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-14T14:20:24', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'eda360d9-8a9b-4c76-9de0-3f5da48538d9'	System	14 Sep 2020 21:20:28
User entered '14 Sep 2020 14:20'	System	14 Sep 2020 21:20:28



**US3462116**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 17:41:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '14 Sep 2020 14:10'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:41:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '14 Sep 2020 16:40'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
Data entry locked.	System	14 Sep 2020 21:16:23
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:41:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-14T17:40:10', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '96642bfa-7796-4476-a268-e056fb9edc81'	System	15 Sep 2020 00:40:23
User entered 'None (1)'	System	15 Sep 2020 00:40:23

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:41:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-14T17:40:12', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '96642bfa-7796-4476-a268-e056fb9edc81'	System	15 Sep 2020 00:40:23
User entered 'No (N)'	System	15 Sep 2020 00:40:23

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:41:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-14T17:40:14', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '96642bfa-7796-4476-a268-e056fb9edc81'	System	15 Sep 2020 00:40:23
User entered 'No (N)'	System	15 Sep 2020 00:40:23

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:41:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-14T17:40:15', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '96642bfa-7796-4476-a268-e056fb9edc81'	System	15 Sep 2020 00:40:23
User entered 'None (1)'	System	15 Sep 2020 00:40:23

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:41:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-14T17:40:18', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '96642bfa-7796-4476-a268-e056fb9edc81'	System	15 Sep 2020 00:40:23
User entered '14 Sep 2020 17:40'	System	15 Sep 2020 00:40:23



**US3462116**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 17:41:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '14 Sep 2020 17:35'	System	14 Sep 2020 21:16:23

**US3462116**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 17:41:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
Data entry locked.	System	14 Sep 2020 21:16:23
User entered 'Day 2'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:41:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:41:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:41:32

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:41:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:41:32

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27



US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:41:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27

**US3462116**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:41:32**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27

**US3462116**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:41:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 21:16:23

**US3462116**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:41:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 21:16:23

**US3462116**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
Data entry locked.	System	14 Sep 2020 21:16:23
User entered 'Day 3'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:41:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-16T17:37:57', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'f510e5e6-e016-4e76-84a3-063596462cec'	System	17 Sep 2020 00:38:11
User entered 'None (1)'	System	17 Sep 2020 00:38:11

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:41:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-16T17:37:59', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'f510e5e6-e016-4e76-84a3-063596462cec'	System	17 Sep 2020 00:38:11
User entered 'No (N)'	System	17 Sep 2020 00:38:11

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:41:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-16T17:38:01', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'f510e5e6-e016-4e76-84a3-063596462cec'	System	17 Sep 2020 00:38:11
User entered 'No (N)'	System	17 Sep 2020 00:38:11



US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:41:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-16T17:38:02', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'f510e5e6-e016-4e76-84a3-063596462cec'	System	17 Sep 2020 00:38:11
User entered 'None (1)'	System	17 Sep 2020 00:38:11

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:41:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-16T17:38:05', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'f510e5e6-e016-4e76-84a3-063596462cec'	System	17 Sep 2020 00:38:11
User entered '16 Sep 2020 17:38'	System	17 Sep 2020 00:38:11

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:41:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 21:16:23

**US3462116**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:41:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
Data entry locked.	System	14 Sep 2020 21:16:23
User entered 'Day 4'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:41:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-17T12:18:42', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '3870f970-dbb4-4d1f-9b69-1073006e65b4'	System	17 Sep 2020 19:18:59
User entered 'None (1)'	System	17 Sep 2020 19:18:59

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:41:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-17T12:18:44', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '3870f970-dbb4-4d1f-9b69-1073006e65b4'	System	17 Sep 2020 19:18:59
User entered 'No (N)'	System	17 Sep 2020 19:18:59

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:41:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-17T12:18:46', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '3870f970-dbb4-4d1f-9b69-1073006e65b4'	System	17 Sep 2020 19:18:59
User entered 'No (N)'	System	17 Sep 2020 19:18:59



US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:41:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-17T12:18:47', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '3870f970-dbb4-4d1f-9b69-1073006e65b4'	System	17 Sep 2020 19:18:59
User entered 'None (1)'	System	17 Sep 2020 19:18:59

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:41:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-17T12:18:49', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '3870f970-dbb4-4d1f-9b69-1073006e65b4'	System	17 Sep 2020 19:18:59
User entered '17 Sep 2020 12:18'	System	17 Sep 2020 19:18:59

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:41:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 21:16:23

**US3462116**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 17:41:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 21:16:23

**US3462116**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
Data entry locked.	System	14 Sep 2020 21:16:23
User entered 'Day 5'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:41:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-18T14:48:31', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'b7086360-5e91-4546-a807-75a1a32d10fd'	System	18 Sep 2020 21:48:47
User entered 'None (1)'	System	18 Sep 2020 21:48:47

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:41:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-18T14:48:34', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'b7086360-5e91-4546-a807-75a1a32d10fd'	System	18 Sep 2020 21:48:47
User entered 'No (N)'	System	18 Sep 2020 21:48:47

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:41:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-18T14:48:37', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'b7086360-5e91-4546-a807-75a1a32d10fd'	System	18 Sep 2020 21:48:47
User entered 'No (N)'	System	18 Sep 2020 21:48:47



US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:41:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-18T14:48:39', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'b7086360-5e91-4546-a807-75a1a32d10fd'	System	18 Sep 2020 21:48:47
User entered 'None (1)'	System	18 Sep 2020 21:48:47

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:41:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-18T14:48:42', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'b7086360-5e91-4546-a807-75a1a32d10fd'	System	18 Sep 2020 21:48:47
User entered '18 Sep 2020 14:48'	System	18 Sep 2020 21:48:47

**US3462116**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:41:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 21:16:23

**US3462116**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:41:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
Data entry locked.	System	14 Sep 2020 21:16:23
User entered 'Day 6'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:41:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-19T12:02:08', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '7a38c54b-9f89-4a16-b796-772fac987461'	System	19 Sep 2020 19:02:20
User entered 'None (1)'	System	19 Sep 2020 19:02:20

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:41:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-19T12:02:11', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '7a38c54b-9f89-4a16-b796-772fac987461'	System	19 Sep 2020 19:02:20
User entered 'No (N)'	System	19 Sep 2020 19:02:20

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:41:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-19T12:02:13', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '7a38c54b-9f89-4a16-b796-772fac987461'	System	19 Sep 2020 19:02:20
User entered 'No (N)'	System	19 Sep 2020 19:02:20



US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:41:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-19T12:02:14', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '7a38c54b-9f89-4a16-b796-772fac987461'	System	19 Sep 2020 19:02:20
User entered 'None (1)'	System	19 Sep 2020 19:02:20

**US3462116**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:41:32**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-19T12:02:17', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '7a38c54b-9f89-4a16-b796-772fac987461'	System	19 Sep 2020 19:02:20
User entered '19 Sep 2020 12:02'	System	19 Sep 2020 19:02:20

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:41:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:41:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 21:16:23

**US3462116**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
Data entry locked.	System	14 Sep 2020 21:16:23
User entered 'Day 7'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:41:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-20T17:14:16', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '129a708b-0432-4200-b1c9-fb1327f345e0'	System	21 Sep 2020 00:14:36
User entered 'None (1)'	System	21 Sep 2020 00:14:36

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:41:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-20T17:14:19', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '129a708b-0432-4200-b1c9-fb1327f345e0'	System	21 Sep 2020 00:14:36
User entered 'No (N)'	System	21 Sep 2020 00:14:36

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:41:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-20T17:14:20', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '129a708b-0432-4200-b1c9-fb1327f345e0'	System	21 Sep 2020 00:14:36
User entered 'No (N)'	System	21 Sep 2020 00:14:36



US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:41:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-20T17:14:22', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '129a708b-0432-4200-b1c9-fb1327f345e0'	System	21 Sep 2020 00:14:36
User entered 'None (1)'	System	21 Sep 2020 00:14:36

US3462116

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:41:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-20T17:14:25', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '129a708b-0432-4200-b1c9-fb1327f345e0'	System	21 Sep 2020 00:14:36
User entered '20 Sep 2020 17:14'	System	21 Sep 2020 00:14:36

**US3462116**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:41:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 21:16:23

**US3462116**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:41:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
Data entry locked.	System	14 Sep 2020 21:16:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:41:32

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-14T14:20:27', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'cd3f73c2-6e96-4cbd-9102-a8145d09edba'	System	14 Sep 2020 21:21:01
User entered 'None (0)'	System	14 Sep 2020 21:21:01

US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:41:32

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-14T14:20:29', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'cd3f73c2-6e96-4cbd-9102-a8145d09edba'	System	14 Sep 2020 21:21:01
User entered 'None (0)'	System	14 Sep 2020 21:21:01

US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:41:32

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-14T14:20:30', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'cd3f73c2-6e96-4cbd-9102-a8145d09edba'	System	14 Sep 2020 21:21:01
User entered 'None (0)'	System	14 Sep 2020 21:21:01



US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:41:32

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-14T14:20:32', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'cd3f73c2-6e96-4cbd-9102-a8145d09edba'	System	14 Sep 2020 21:21:01
User entered 'None (0)'	System	14 Sep 2020 21:21:01

US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:41:32

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-14T14:20:35', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'cd3f73c2-6e96-4cbd-9102-a8145d09edba'	System	14 Sep 2020 21:21:01
User entered 'None (0)'	System	14 Sep 2020 21:21:01

US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:41:32

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-14T14:20:37', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'cd3f73c2-6e96-4cbd-9102-a8145d09edba'	System	14 Sep 2020 21:21:01
User entered 'None (0)'	System	14 Sep 2020 21:21:01

US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:41:32

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)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-14T14:20:45', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'cd3f73c2-6e96-4cbd-9102-a8145d09edba'	System	14 Sep 2020 21:21:01
User entered 'No (N)'	System	14 Sep 2020 21:21:01

US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:41:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-14T14:20:47', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'cd3f73c2-6e96-4cbd-9102-a8145d09edba'	System	14 Sep 2020 21:21:01
User entered '14 Sep 2020 14:20'	System	14 Sep 2020 21:21:01

**US3462116**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:41:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '14 Sep 2020 14:10'	System	14 Sep 2020 21:16:23

**US3462116**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:41:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '14 Sep 2020 16:40'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
Data entry locked.	System	14 Sep 2020 21:16:23
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 21:16:23



US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:41:32

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-14T17:40:21', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'f49e27f6-d118-4a2f-9c7c-fbf791c1c10d'	System	15 Sep 2020 00:40:35
User entered 'None (0)'	System	15 Sep 2020 00:40:35

US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:41:32

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-14T17:40:22', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'f49e27f6-d118-4a2f-9c7c-fbf791c1c10d'	System	15 Sep 2020 00:40:35
User entered 'None (0)'	System	15 Sep 2020 00:40:35

US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:41:32

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-14T17:40:23', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'f49e27f6-d118-4a2f-9c7c-fbf791c1c10d'	System	15 Sep 2020 00:40:35
User entered 'None (0)'	System	15 Sep 2020 00:40:35

US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:41:32

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-14T17:40:25', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'f49e27f6-d118-4a2f-9c7c-fbf791c1c10d'	System	15 Sep 2020 00:40:35
User entered 'None (0)'	System	15 Sep 2020 00:40:35

US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:41:32

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-14T17:40:26', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'f49e27f6-d118-4a2f-9c7c-fbf791c1c10d'	System	15 Sep 2020 00:40:35
User entered 'None (0)'	System	15 Sep 2020 00:40:35

US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:41:32

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-14T17:40:27', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'f49e27f6-d118-4a2f-9c7c-fbf791c1c10d'	System	15 Sep 2020 00:40:35
User entered 'None (0)'	System	15 Sep 2020 00:40:35

US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:41:32

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)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-14T17:40:29', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'f49e27f6-d118-4a2f-9c7c-fbf791c1c10d'	System	15 Sep 2020 00:40:35
User entered 'No (N)'	System	15 Sep 2020 00:40:35

US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:41:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-14T17:40:32', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'f49e27f6-d118-4a2f-9c7c-fbf791c1c10d'	System	15 Sep 2020 00:40:35
User entered '14 Sep 2020 17:40'	System	15 Sep 2020 00:40:35



**US3462116**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:41:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '14 Sep 2020 17:35'	System	14 Sep 2020 21:16:23

**US3462116**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:41:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
Data entry locked.	System	14 Sep 2020 21:16:23
User entered 'Day 2'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:41:32

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27

**US3462116**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:41:32**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27

US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:41:32

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27

US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:41:32

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27

**US3462116**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:41:32**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27



**US3462116**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:41:32**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27

US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:41:32

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)	26 Feb 2021 06:25:27

**US3462116**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:41:32**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27

**US3462116**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:41:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 21:16:23

**US3462116**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:41:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 21:16:23

**US3462116**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
Data entry locked.	System	14 Sep 2020 21:16:23
User entered 'Day 3'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:41:32

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-16T17:38:08', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '3ff8c28b-cd26-439f-bbe4-d9685bf5ae87'	System	17 Sep 2020 00:38:21
User entered 'None (0)'	System	17 Sep 2020 00:38:21

US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:41:32

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-16T17:38:09', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '3ff8c28b-cd26-439f-bbe4-d9685bf5ae87'	System	17 Sep 2020 00:38:21
User entered 'None (0)'	System	17 Sep 2020 00:38:21



US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:41:32

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-16T17:38:10', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '3ff8c28b-cd26-439f-bbe4-d9685bf5ae87'	System	17 Sep 2020 00:38:21
User entered 'None (0)'	System	17 Sep 2020 00:38:21

US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:41:32

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-16T17:38:11', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '3ff8c28b-cd26-439f-bbe4-d9685bf5ae87'	System	17 Sep 2020 00:38:21
User entered 'None (0)'	System	17 Sep 2020 00:38:21

US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:41:32

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-16T17:38:12', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '3ff8c28b-cd26-439f-bbe4-d9685bf5ae87'	System	17 Sep 2020 00:38:21
User entered 'None (0)'	System	17 Sep 2020 00:38:21

US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:41:32

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-16T17:38:13', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '3ff8c28b-cd26-439f-bbe4-d9685bf5ae87'	System	17 Sep 2020 00:38:21
User entered 'None (0)'	System	17 Sep 2020 00:38:21

US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:41:32

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)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-16T17:38:15', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '3ff8c28b-cd26-439f-bbe4-d9685bf5ae87'	System	17 Sep 2020 00:38:21
User entered 'No (N)'	System	17 Sep 2020 00:38:21

US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:41:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-16T17:38:17', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '3ff8c28b-cd26-439f-bbe4-d9685bf5ae87'	System	17 Sep 2020 00:38:21
User entered '16 Sep 2020 17:38'	System	17 Sep 2020 00:38:21

**US3462116**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:41:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 21:16:23

**US3462116**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:41:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 21:16:23



US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:41:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
Data entry locked.	System	14 Sep 2020 21:16:23
User entered 'Day 4'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:41:32

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-17T12:18:52', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '672d31da-9773-4d0f-aeb6-b0877fd1a24d'	System	17 Sep 2020 19:19:07
User entered 'None (0)'	System	17 Sep 2020 19:19:07

US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:41:32

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-17T12:18:54', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '672d31da-9773-4d0f-aeb6-b0877fd1a24d'	System	17 Sep 2020 19:19:07
User entered 'None (0)'	System	17 Sep 2020 19:19:07

US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:41:32

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-17T12:18:55', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '672d31da-9773-4d0f-aeb6-b0877fd1a24d'	System	17 Sep 2020 19:19:07
User entered 'None (0)'	System	17 Sep 2020 19:19:07

US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:41:32

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-17T12:18:56', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '672d31da-9773-4d0f-aeb6-b0877fd1a24d'	System	17 Sep 2020 19:19:07
User entered 'None (0)'	System	17 Sep 2020 19:19:07

US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:41:32

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-17T12:18:57', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '672d31da-9773-4d0f-aeb6-b0877fd1a24d'	System	17 Sep 2020 19:19:07
User entered 'None (0)'	System	17 Sep 2020 19:19:07

US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:41:32

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-17T12:18:58', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '672d31da-9773-4d0f-aeb6-b0877fd1a24d'	System	17 Sep 2020 19:19:07
User entered 'None (0)'	System	17 Sep 2020 19:19:07

US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:41:32

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)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-17T12:19:00', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '672d31da-9773-4d0f-aeb6-b0877fd1a24d'	System	17 Sep 2020 19:19:07
User entered 'No (N)'	System	17 Sep 2020 19:19:07



US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:41:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-17T12:19:02', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '672d31da-9773-4d0f-aeb6-b0877fd1a24d'	System	17 Sep 2020 19:19:07
User entered '17 Sep 2020 12:19'	System	17 Sep 2020 19:19:07

**US3462116**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:41:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:41:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 21:16:23

**US3462116**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
Data entry locked.	System	14 Sep 2020 21:16:23
User entered 'Day 5'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:41:32

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-18T14:48:46', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '18216270-eb37-4b33-873b-24092eaf9095'	System	18 Sep 2020 21:49:05
User entered 'None (0)'	System	18 Sep 2020 21:49:05

US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:41:32

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-18T14:48:48', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '18216270-eb37-4b33-873b-24092eaf9095'	System	18 Sep 2020 21:49:05
User entered 'None (0)'	System	18 Sep 2020 21:49:05

US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:41:32

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-18T14:48:49', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '18216270-eb37-4b33-873b-24092eaf9095'	System	18 Sep 2020 21:49:05
User entered 'None (0)'	System	18 Sep 2020 21:49:05

US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:41:32

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-18T14:48:51', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '18216270-eb37-4b33-873b-24092eaf9095'	System	18 Sep 2020 21:49:05
User entered 'None (0)'	System	18 Sep 2020 21:49:05



US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:41:32

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-18T14:48:53', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '18216270-eb37-4b33-873b-24092eaf9095'	System	18 Sep 2020 21:49:05
User entered 'None (0)'	System	18 Sep 2020 21:49:05

US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:41:32

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-18T14:48:56', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '18216270-eb37-4b33-873b-24092eaf9095'	System	18 Sep 2020 21:49:05
User entered 'None (0)'	System	18 Sep 2020 21:49:05

US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:41:32

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)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-18T14:48:59', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '18216270-eb37-4b33-873b-24092eaf9095'	System	18 Sep 2020 21:49:05
User entered 'No (N)'	System	18 Sep 2020 21:49:05

**US3462116**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:41:32**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-18T14:49:02', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '18216270-eb37-4b33-873b-24092eaf9095'	System	18 Sep 2020 21:49:05
User entered '18 Sep 2020 14:49'	System	18 Sep 2020 21:49:05

**US3462116**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:41:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 21:16:23

**US3462116**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:41:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 21:16:23

**US3462116**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
Data entry locked.	System	14 Sep 2020 21:16:23
User entered 'Day 6'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:41:32

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-19T12:02:21', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '09a63f3f-879d-47ac-9376-2f10d7564a7c'	System	19 Sep 2020 19:02:54
User entered 'None (0)'	System	19 Sep 2020 19:02:54



US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:41:32

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-19T12:02:22', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '09a63f3f-879d-47ac-9376-2f10d7564a7c'	System	19 Sep 2020 19:02:54
User entered 'None (0)'	System	19 Sep 2020 19:02:54

US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:41:32

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-19T12:02:24', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '09a63f3f-879d-47ac-9376-2f10d7564a7c'	System	19 Sep 2020 19:02:54
User entered 'None (0)'	System	19 Sep 2020 19:02:54

US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:41:32

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-19T12:02:25', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '09a63f3f-879d-47ac-9376-2f10d7564a7c'	System	19 Sep 2020 19:02:54
User entered 'None (0)'	System	19 Sep 2020 19:02:54

US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:41:32

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-19T12:02:26', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '09a63f3f-879d-47ac-9376-2f10d7564a7c'	System	19 Sep 2020 19:02:54
User entered 'None (0)'	System	19 Sep 2020 19:02:54

US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:41:32

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-19T12:02:28', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '09a63f3f-879d-47ac-9376-2f10d7564a7c'	System	19 Sep 2020 19:02:54
User entered 'None (0)'	System	19 Sep 2020 19:02:54

US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:41:32

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)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-19T12:02:46', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '09a63f3f-879d-47ac-9376-2f10d7564a7c'	System	19 Sep 2020 19:02:54
User entered 'No (N)'	System	19 Sep 2020 19:02:54

US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:41:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-19T12:02:49', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '09a63f3f-879d-47ac-9376-2f10d7564a7c'	System	19 Sep 2020 19:02:54
User entered '19 Sep 2020 12:02'	System	19 Sep 2020 19:02:54

**US3462116**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:41:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 21:16:23



**US3462116**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:41:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 21:16:23

**US3462116**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
Data entry locked.	System	14 Sep 2020 21:16:23
User entered 'Day 7'	System	14 Sep 2020 21:16:23

US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:41:32

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-20T17:14:29', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '0b9e4cb8-1f5f-4b71-9d91-061cc33e5d1d'	System	21 Sep 2020 00:14:52
User entered 'None (0)'	System	21 Sep 2020 00:14:52

US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:41:32

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-20T17:14:31', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '0b9e4cb8-1f5f-4b71-9d91-061cc33e5d1d'	System	21 Sep 2020 00:14:52
User entered 'None (0)'	System	21 Sep 2020 00:14:52

US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:41:32

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-20T17:14:32', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '0b9e4cb8-1f5f-4b71-9d91-061cc33e5d1d'	System	21 Sep 2020 00:14:52
User entered 'None (0)'	System	21 Sep 2020 00:14:52

US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:41:32

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-20T17:14:34', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '0b9e4cb8-1f5f-4b71-9d91-061cc33e5d1d'	System	21 Sep 2020 00:14:52
User entered 'None (0)'	System	21 Sep 2020 00:14:52

US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:41:32

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-20T17:14:35', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '0b9e4cb8-1f5f-4b71-9d91-061cc33e5d1d'	System	21 Sep 2020 00:14:52
User entered 'None (0)'	System	21 Sep 2020 00:14:52

US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:41:32

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-20T17:14:37', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '0b9e4cb8-1f5f-4b71-9d91-061cc33e5d1d'	System	21 Sep 2020 00:14:52
User entered 'None (0)'	System	21 Sep 2020 00:14:52



US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:41:32

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)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-20T17:14:41', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '0b9e4cb8-1f5f-4b71-9d91-061cc33e5d1d'	System	21 Sep 2020 00:14:52
User entered 'No (N)'	System	21 Sep 2020 00:14:52

US3462116

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:41:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-09-20T17:14:43', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '0b9e4cb8-1f5f-4b71-9d91-061cc33e5d1d'	System	21 Sep 2020 00:14:52
User entered '20 Sep 2020 17:14'	System	21 Sep 2020 00:14:52

**US3462116**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:41:32**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 21:16:23

**US3462116**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:41:32**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 21:16:23

US3462116

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 15:08:24

US3462116

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '21 Sep 2020'	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 15:08:24

US3462116

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 15:08:24

US3462116

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:32

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 15:08:24



US3462116

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 15:08:30

**US3462116**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:41:32**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User entered 'I'	System	04 Nov 2020 15:08:30

US3462116

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 15:08:55

US3462116

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '28 Sep 2020'	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 15:08:55

US3462116

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 15:08:55

US3462116

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:32

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 15:08:55

US3462116

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 15:09:01

**US3462116**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:41:32**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User entered 'I'	System	04 Nov 2020 15:09:01



US3462116

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 15:09:17

**US3462116**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:41:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '05 Oct 2020'	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 15:09:17

US3462116

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 15:09:17

US3462116

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:32

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 15:09:17

US3462116

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	05 Nov 2020 19:32:39

**US3462116**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:41:32**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User entered 'I'	System	05 Nov 2020 19:32:39

US3462116

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:41:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	05 Nov 2020 19:32:54

US3462116

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:41:32

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '13 Oct 2020'	(b) (4) Danuel Hamlin (b) (4)	05 Nov 2020 19:32:54



US3462116

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:41:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'Clinic (Clinic)'	(b) (4) Danuel Hamlin (b) (4)	05 Nov 2020 19:32:54

**US3462116**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:41:32**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User entered 'VISIT3'	System	05 Nov 2020 19:32:54

US3462116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	05 Nov 2020 19:33:03

US3462116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	05 Nov 2020 19:33:03

US3462116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	05 Nov 2020 19:33:03

**US3462116**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:41:32**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User entered empty.	System	05 Nov 2020 19:33:03

US3462116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	05 Nov 2020 19:33:03

US3462116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	05 Nov 2020 19:33:03



US3462116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	05 Nov 2020 19:33:03

US3462116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	05 Nov 2020 19:33:03

**US3462116**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:41:32**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User entered empty.	System	05 Nov 2020 19:33:03

US3462116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:32

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	05 Nov 2020 19:33:03

**US3462116**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:41:32**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User entered empty.	System	05 Nov 2020 19:33:03

US3462116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	05 Nov 2020 19:33:03

**US3462116**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:41:32**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User entered empty.	System	05 Nov 2020 19:33:03

US3462116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	05 Nov 2020 19:33:03



**US3462116**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:41:32**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User entered empty.	System	05 Nov 2020 19:33:03

**US3462116**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:41:32**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31

**US3462116**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:41:32**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31

US3462116

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:41:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	05 Nov 2020 19:33:08

US3462116

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:41:32

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	05 Nov 2020 19:33:08

US3462116

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	05 Nov 2020 19:33:28

US3462116

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:32

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '13 Oct 2020'	(b) (4) Danuel Hamlin (b) (4)	05 Nov 2020 19:33:28

US3462116

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:32

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered '15:50'	(b) (4) Danuel Hamlin (b) (4)	05 Nov 2020 19:33:28



**US3462116**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:41:32**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User entered '13 Oct 2020 15:50'	System	05 Nov 2020 19:33:28

US3462116

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:25:11
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	05 Nov 2020 19:33:33

**US3462116**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:41:32**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User entered 'I'	System	05 Nov 2020 19:33:33

**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
Data entry locked.	System	11 Aug 2020 19:31:39
User entered 'Day 64'	System	11 Aug 2020 19:31:39

**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[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)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-10-13T14:12:07', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '97137beb-fc64-41da-bb8a-f468fc5e35e1'	System	13 Oct 2020 21:12:23
User entered 'No (N)'	System	13 Oct 2020 21:12:23

**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

Have you been exposed to someone with 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)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-10-13T14:12:11', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '97137beb-fc64-41da-bb8a-f468fc5e35e1'	System	13 Oct 2020 21:12:23
User entered 'No (N)'	System	13 Oct 2020 21:12:23

**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-10-13T14:12:18', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '97137beb-fc64-41da-bb8a-f468fc5e35e1'	System	13 Oct 2020 21:12:23
User entered '13 Oct 2020 14:12:18'	System	13 Oct 2020 21:12:23

**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
Data entry locked.	System	11 Aug 2020 19:31:39
User entered '11 Oct 2020 00:01'	System	11 Aug 2020 19:31:39



**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
Data entry locked.	System	11 Aug 2020 19:31:39
User entered '15 Oct 2020 23:59'	System	11 Aug 2020 19:31:39

**US3462116**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
Data entry locked.	System	11 Aug 2020 19:31:39
User entered 'Day 71'	System	11 Aug 2020 19:31:39

**US3462116**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[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)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-10-19T14:03:50', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '62665bfa-98f0-4e6d-bc00-99c80f8affa0'	System	19 Oct 2020 21:04:30
User entered 'No (N)'	System	19 Oct 2020 21:04:30

**US3462116**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Have you been exposed to someone with 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)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-10-19T14:03:53', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '62665bfa-98f0-4e6d-bc00-99c80f8affa0'	System	19 Oct 2020 21:04:30
User entered 'No (N)'	System	19 Oct 2020 21:04:30

**US3462116**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-10-19T14:03:56', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '62665bfa-98f0-4e6d-bc00-99c80f8affa0'	System	19 Oct 2020 21:04:30
User entered '19 Oct 2020 14:03:56'	System	19 Oct 2020 21:04:30

**US3462116**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
Data entry locked.	System	11 Aug 2020 19:31:39
User entered '18 Oct 2020 00:01'	System	11 Aug 2020 19:31:39

**US3462116**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
Data entry locked.	System	11 Aug 2020 19:31:39
User entered '22 Oct 2020 23:59'	System	11 Aug 2020 19:31:39

**US3462116**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
Data entry locked.	System	11 Aug 2020 19:31:39
User entered 'Day 78'	System	11 Aug 2020 19:31:39



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**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[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)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-10-25T12:48:41', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '3eebf8b5-b912-4ba5-855e-63e1a3e9b8bc'	System	25 Oct 2020 19:48:53
User entered 'No (N)'	System	25 Oct 2020 19:48:53

**US3462116**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

Have you been exposed to someone with 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)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-10-25T12:48:44', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '3eebf8b5-b912-4ba5-855e-63e1a3e9b8bc'	System	25 Oct 2020 19:48:53
User entered 'No (N)'	System	25 Oct 2020 19:48:53

**US3462116**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-10-25T12:48:47', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '3eebf8b5-b912-4ba5-855e-63e1a3e9b8bc'	System	25 Oct 2020 19:48:53
User entered '25 Oct 2020 12:48:47'	System	25 Oct 2020 19:48:53

**US3462116**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
Data entry locked.	System	11 Aug 2020 19:31:39
User entered '25 Oct 2020 00:01'	System	11 Aug 2020 19:31:39

**US3462116**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
Data entry locked.	System	11 Aug 2020 19:31:39
User entered '29 Oct 2020 23:59'	System	11 Aug 2020 19:31:39

**US3462116**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
Data entry locked.	System	11 Aug 2020 19:31:39
User entered 'Day 92'	System	11 Aug 2020 19:31:39

**US3462116**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[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)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-11-08T23:04:48', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'efe4ff86-1621-4184-b1e3-41eaac66f7c5'	System	09 Nov 2020 07:04:58
User entered 'No (N)'	System	09 Nov 2020 07:04:58

US3462116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:32

Have you been exposed to someone with 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)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-11-08T23:04:51', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'efe4ff86-1621-4184-b1e3-41eaac66f7c5'	System	09 Nov 2020 07:04:58
User entered 'No (N)'	System	09 Nov 2020 07:04:58



**US3462116**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-11-08T23:04:55', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'efe4ff86-1621-4184-b1e3-41eaac66f7c5'	System	09 Nov 2020 07:04:58
User entered '08 Nov 2020 23:04:55'	System	09 Nov 2020 07:04:58

**US3462116**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
Data entry locked.	System	11 Aug 2020 19:31:39
User entered '08 Nov 2020 00:01'	System	11 Aug 2020 19:31:39

**US3462116**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
Data entry locked.	System	11 Aug 2020 19:31:39
User entered '12 Nov 2020 23:59'	System	11 Aug 2020 19:31:39

**US3462116**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
Data entry locked.	System	11 Aug 2020 19:31:39
User entered 'Day 99'	System	11 Aug 2020 19:31:39

**US3462116**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[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)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-11-17T13:34:21', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '6fe7f955-fc06-4086-aa26-4639abae0db'	System	17 Nov 2020 21:34:32
User entered 'No (N)'	System	17 Nov 2020 21:34:32

**US3462116**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Have you been exposed to someone with 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)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-11-17T13:34:25', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '6fe7f955-fc06-4086-aa26-4639abae0db'	System	17 Nov 2020 21:34:32
User entered 'No (N)'	System	17 Nov 2020 21:34:32

**US3462116**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-11-17T13:34:28', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '6fe7f955-fc06-4086-aa26-4639abae0db'	System	17 Nov 2020 21:34:32
User entered '17 Nov 2020 13:34:28'	System	17 Nov 2020 21:34:32

**US3462116**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
Data entry locked.	System	11 Aug 2020 19:31:39
User entered '15 Nov 2020 00:01'	System	11 Aug 2020 19:31:39



**US3462116**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:25:27
Data entry locked.	System	11 Aug 2020 19:31:39
User entered '19 Nov 2020 23:59'	System	11 Aug 2020 19:31:39

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[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 (828bc5fe3770f41d)', Time: '2020-11-21T21:27:05', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '3a63a66a-8a02-4924-b0f4-6353edec0f63'	System	22 Nov 2020 05:31:24
User entered 'No (N)'	System	22 Nov 2020 05:31:24

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

Have you been exposed to someone with 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 (828bc5fe3770f41d)', Time: '2020-11-21T21:27:09', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '3a63a66a-8a02-4924-b0f4-6353edec0f63'	System	22 Nov 2020 05:31:24
User entered 'No (N)'	System	22 Nov 2020 05:31:24

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-11-21T21:27:12', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '3a63a66a-8a02-4924-b0f4-6353edec0f63'	System	22 Nov 2020 05:31:24
User entered '21 Nov 2020 21:27:12'	System	22 Nov 2020 05:31:24

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 03:56:16



**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[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 (828bc5fe3770f41d)', Time: '2020-11-26T10:31:28', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '38ebe542-306f-489f-9d0a-14d4955472c8'	System	26 Nov 2020 18:31:37
User entered 'No (N)'	System	26 Nov 2020 18:31:37

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Have you been exposed to someone with 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 (828bc5fe3770f41d)', Time: '2020-11-26T10:31:31', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '38ebe542-306f-489f-9d0a-14d4955472c8'	System	26 Nov 2020 18:31:37
User entered 'No (N)'	System	26 Nov 2020 18:31:37

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 17:41:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-11-26T10:31:33', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '38ebe542-306f-489f-9d0a-14d4955472c8'	System	26 Nov 2020 18:31:37
User entered '26 Nov 2020 10:31:33'	System	26 Nov 2020 18:31:37

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[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 (828bc5fe3770f41d)', Time: '2020-12-03T03:50:20', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '40ea98b9-ecc5-4d01-a789-4bffd3477fe5'	System	03 Dec 2020 11:50:29
User entered 'No (N)'	System	03 Dec 2020 11:50:29

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Have you been exposed to someone with 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 (828bc5fe3770f41d)', Time: '2020-12-03T03:50:22', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '40ea98b9-ecc5-4d01-a789-4bffd3477fe5'	System	03 Dec 2020 11:50:29
User entered 'No (N)'	System	03 Dec 2020 11:50:29



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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 17:41:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-12-03T03:50:25', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '40ea98b9-ecc5-4d01-a789-4bffd3477fe5' User entered '03 Dec 2020 03:50:25'	System	03 Dec 2020 11:50:29
	System	03 Dec 2020 11:50:29

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 03:56:16

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[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 (828bc5fe3770f41d)', Time: '2020-12-10T08:58:57', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '452c39cf-8e22-4ceb-83db-aa7899f82a49'	System	10 Dec 2020 16:59:09
User entered 'No (N)'	System	10 Dec 2020 16:59:09

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Have you been exposed to someone with 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 (828bc5fe3770f41d)', Time: '2020-12-10T08:59:00', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '452c39cf-8e22-4ceb-83db-aa7899f82a49'	System	10 Dec 2020 16:59:09
User entered 'No (N)'	System	10 Dec 2020 16:59:09

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-12-10T08:59:03', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '452c39cf-8e22-4ceb-83db-aa7899f82a49'	System	10 Dec 2020 16:59:09
User entered '10 Dec 2020 08:59:03'	System	10 Dec 2020 16:59:09

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 03:56:16



**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[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 (828bc5fe3770f41d)', Time: '2020-12-17T10:14:33', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'c1196b37-ab34-4f1b-86ad-21c64973763e'	System	17 Dec 2020 18:14:40
User entered 'No (N)'	System	17 Dec 2020 18:14:40

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Have you been exposed to someone with 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 (828bc5fe3770f41d)', Time: '2020-12-17T10:14:35', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'c1196b37-ab34-4f1b-86ad-21c64973763e'	System	17 Dec 2020 18:14:40
User entered 'No (N)'	System	17 Dec 2020 18:14:40

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-12-17T10:14:38', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'c1196b37-ab34-4f1b-86ad-21c64973763e' User entered '17 Dec 2020 10:14:38'	System	17 Dec 2020 18:14:40
	System	17 Dec 2020 18:14:40

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 03:56:16



**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[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 (828bc5fe3770f41d)', Time: '2020-12-24T10:32:14', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '411872d1-3adb-4e24-9618-00915933444c'	System	24 Dec 2020 18:32:21
User entered 'No (N)'	System	24 Dec 2020 18:32:21

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Have you been exposed to someone with 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 (828bc5fe3770f41d)', Time: '2020-12-24T10:32:15', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '411872d1-3adb-4e24-9618-00915933444c'	System	24 Dec 2020 18:32:21
User entered 'No (N)'	System	24 Dec 2020 18:32:21

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2020-12-24T10:32:18', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '411872d1-3adb-4e24-9618-00915933444c'	System	24 Dec 2020 18:32:21
User entered '24 Dec 2020 10:32:18'	System	24 Dec 2020 18:32:21

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 03:56:16



**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[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 (828bc5fe3770f41d)', Time: '2021-01-11T09:06:01', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '81328ea6-36c5-404a-8a8d-ca9fefaf170ae'	System	11 Jan 2021 17:06:14
User entered 'No (N)'	System	11 Jan 2021 17:06:14

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Have you been exposed to someone with 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 (828bc5fe3770f41d)', Time: '2021-01-11T09:06:03', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '81328ea6-36c5-404a-8a8d-ca9fefaf170ae'	System	11 Jan 2021 17:06:14
User entered 'No (N)'	System	11 Jan 2021 17:06:14

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2021-01-11T09:06:06', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '81328ea6-36c5-404a-8a8d-ca9fefa170ae'	System	11 Jan 2021 17:06:14
User entered '11 Jan 2021 09:06:06'	System	11 Jan 2021 17:06:14

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[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 (828bc5fe3770f41d)', Time: '2021-01-16T13:19:55', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '9899ba43-4de2-4154-b577-ea23fb6a5299'	System	16 Jan 2021 21:20:03
User entered 'No (N)'	System	16 Jan 2021 21:20:03



**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

Have you been exposed to someone with 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 (828bc5fe3770f41d)', Time: '2021-01-16T13:19:57', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '9899ba43-4de2-4154-b577-ea23fb6a5299'	System	16 Jan 2021 21:20:03
User entered 'No (N)'	System	16 Jan 2021 21:20:03

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2021-01-16T13:20:00', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '9899ba43-4de2-4154-b577-ea23fb6a5299'	System	16 Jan 2021 21:20:03
User entered '16 Jan 2021 13:20:00'	System	16 Jan 2021 21:20:03

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 03:56:16



**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[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 (828bc5fe3770f41d)', Time: '2021-01-29T11:03:14', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'a7937447-a325-4af7-9b78-c49792e30c0e'	System	29 Jan 2021 19:03:24
User entered 'No (N)'	System	29 Jan 2021 19:03:24

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

Have you been exposed to someone with 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 (828bc5fe3770f41d)', Time: '2021-01-29T11:03:16', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'a7937447-a325-4af7-9b78-c49792e30c0e'	System	29 Jan 2021 19:03:24
User entered 'No (N)'	System	29 Jan 2021 19:03:24

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2021-01-29T11:03:18', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'a7937447-a325-4af7-9b78-c49792e30c0e' User entered '29 Jan 2021 11:03:18'	System	29 Jan 2021 19:03:24

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[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 (828bc5fe3770f41d)', Time: '2021-02-06T16:03:26', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'c49efc14-1b38-40b5-bf3c-11c4eaec5a1b'	System	07 Feb 2021 00:05:11
User entered 'No (N)'	System	07 Feb 2021 00:05:11

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Have you been exposed to someone with 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 (828bc5fe3770f41d)', Time: '2021-02-06T16:03:28', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'c49efc14-1b38-40b5-bf3c-11c4eaec5a1b'	System	07 Feb 2021 00:05:11
User entered 'No (N)'	System	07 Feb 2021 00:05:11



**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2021-02-06T16:03:31', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'c49efc14-1b38-40b5-bf3c-11c4eaec5a1b'	System	07 Feb 2021 00:05:11
User entered '06 Feb 2021 16:03:31'	System	07 Feb 2021 00:05:11

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[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 (828bc5fe3770f41d)', Time: '2021-02-13T01:03:59', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'de366d0d-5685-4561-90fd-dc7fec628f24'	System	13 Feb 2021 09:04:08
User entered 'No (N)'	System	13 Feb 2021 09:04:08

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

Have you been exposed to someone with 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 (828bc5fe3770f41d)', Time: '2021-02-13T01:04:01', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'de366d0d-5685-4561-90fd-dc7fec628f24'	System	13 Feb 2021 09:04:08
User entered 'No (N)'	System	13 Feb 2021 09:04:08

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2021-02-13T01:04:04', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'de366d0d-5685-4561-90fd-dc7fec628f24'	System	13 Feb 2021 09:04:08
User entered '13 Feb 2021 01:04:04'	System	13 Feb 2021 09:04:08

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 03:56:16



**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[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 (828bc5fe3770f41d)', Time: '2021-02-19T11:27:44', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '42abc725-75c0-4832-a298-06cb668e46be'	System	19 Feb 2021 21:55:05
User entered 'No (N)'	System	19 Feb 2021 21:55:05

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

Have you been exposed to someone with 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 (828bc5fe3770f41d)', Time: '2021-02-19T11:27:45', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '42abc725-75c0-4832-a298-06cb668e46be'	System	19 Feb 2021 21:55:05
User entered 'No (N)'	System	19 Feb 2021 21:55:05

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2021-02-19T11:27:49', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '42abc725-75c0-4832-a298-06cb668e46be' User entered '19 Feb 2021 11:27:49'	System	19 Feb 2021 21:55:05
	System	19 Feb 2021 21:55:05

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 03:56:16



**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[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 (828bc5fe3770f41d)', Time: '2021-02-25T21:44:49-08:00', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '0cbcc101-1cb2-4df1-b91e-0b591187a1e7'	System	26 Feb 2021 08:12:05
User entered 'No (N)'	System	26 Feb 2021 08:12:05

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

Have you been exposed to someone with 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 (828bc5fe3770f41d)', Time: '2021-02-25T21:44:51-08:00', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '0cbcc101-1cb2-4df1-b91e-0b591187a1e7'	System	26 Feb 2021 08:12:05
User entered 'No (N)'	System	26 Feb 2021 08:12:05

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828bc5fe3770f41d)', Time: '2021-02-25T21:44:54-08:00', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '0cbcc101-1cb2-4df1-b91e-0b591187a1e7'	System	26 Feb 2021 08:12:05
User entered '25 Feb 2021 21:44:54'	System	26 Feb 2021 08:12:05

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[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 (88ccd327335a9f7d)', Time: '2021-03-04T14:53:23-08:00', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '0c7ee49d-99c1-4121-9ed4-b08db8b37d53'	System	04 Mar 2021 22:53:34
User entered 'No (N)'	System	04 Mar 2021 22:53:34

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

Have you been exposed to someone with 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 (88ccd327335a9f7d)', Time: '2021-03-04T14:53:27-08:00', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '0c7ee49d-99c1-4121-9ed4-b08db8b37d53'	System	04 Mar 2021 22:53:34
User entered 'No (N)'	System	04 Mar 2021 22:53:34



**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88ccd327335a9f7d)', Time: '2021-03-04T14:53:32-08:00', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '0c7ee49d-99c1-4121-9ed4-b08db8b37d53'	System	04 Mar 2021 22:53:34
User entered '04 Mar 2021 14:53:32'	System	04 Mar 2021 22:53:34

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[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 (88ccd327335a9f7d)', Time: '2021-03-11T09:55:01-08:00', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'f33a992c-cd37-4096-bd7a-5aac29c39e98'	System	11 Mar 2021 17:55:08
User entered 'No (N)'	System	11 Mar 2021 17:55:08

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

Have you been exposed to someone with 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 (88ccd327335a9f7d)', Time: '2021-03-11T09:55:03-08:00', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'f33a992c-cd37-4096-bd7a-5aac29c39e98'	System	11 Mar 2021 17:55:08
User entered 'No (N)'	System	11 Mar 2021 17:55:08

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88ccd327335a9f7d)', Time: '2021-03-11T09:55:06-08:00', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'f33a992c-cd37-4096-bd7a-5aac29c39e98'	System	11 Mar 2021 17:55:08
User entered '11 Mar 2021 09:55:06'	System	11 Mar 2021 17:55:08

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 03:56:16



**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[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 (88ccd327335a9f7d)', Time: '2021-03-18T00:01:32-07:00', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '44e89b69-2706-4530-a543-f37bc863fd73'	System	18 Mar 2021 07:01:43
User entered 'No (N)'	System	18 Mar 2021 07:01:43

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

Have you been exposed to someone with 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 (88ccd327335a9f7d)', Time: '2021-03-18T00:01:34-07:00', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '44e89b69-2706-4530-a543-f37bc863fd73'	System	18 Mar 2021 07:01:43
User entered 'No (N)'	System	18 Mar 2021 07:01:43

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88ccd327335a9f7d)', Time: '2021-03-18T00:01:38-07:00', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '44e89b69-2706-4530-a543-f37bc863fd73' User entered '18 Mar 2021 00:01:38'	System	18 Mar 2021 07:01:43
	System	18 Mar 2021 07:01:43

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 03:56:16



**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[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 (88ccd327335a9f7d)', Time: '2021-03-25T13:39:01-07:00', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '0b328a89-4465-402f-9a79-e51bcfc47893'	System	25 Mar 2021 20:39:11
User entered 'No (N)'	System	25 Mar 2021 20:39:11

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

Have you been exposed to someone with 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 (88ccd327335a9f7d)', Time: '2021-03-25T13:39:03-07:00', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '0b328a89-4465-402f-9a79-e51bcfc47893'	System	25 Mar 2021 20:39:11
User entered 'No (N)'	System	25 Mar 2021 20:39:11

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88ccd327335a9f7d)', Time: '2021-03-25T13:39:07-07:00', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '0b328a89-4465-402f-9a79-e51bcfc47893'	System	25 Mar 2021 20:39:11
User entered '25 Mar 2021 13:39:07'	System	25 Mar 2021 20:39:11

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[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 (88ccd327335a9f7d)', Time: '2021-04-01T01:12:17-07:00', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '05dc4a48-70f6-4649-97c4-67b8d6e508af' User entered 'No (N)'	System	01 Apr 2021 08:12:24
	System	01 Apr 2021 08:12:24

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

Have you been exposed to someone with 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 (88ccd327335a9f7d)', Time: '2021-04-01T01:12:18-07:00', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '05dc4a48-70f6-4649-97c4-67b8d6e508af'	System	01 Apr 2021 08:12:24
User entered 'No (N)'	System	01 Apr 2021 08:12:24



**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88ccd327335a9f7d)', Time: '2021-04-01T01:12:21-07:00', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '05dc4a48-70f6-4649-97c4-67b8d6e508af' User entered '01 Apr 2021 01:12:21'	System	01 Apr 2021 08:12:24
	System	01 Apr 2021 08:12:24

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[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 (88ccd327335a9f7d)', Time: '2021-04-08T09:17:52-07:00', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '8b3015f7-88f3-4494-b66c-14de47f021fb'	System	08 Apr 2021 16:19:12
User entered 'Yes (Y)'	System	08 Apr 2021 16:19:12

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

Have you been exposed to someone with 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 (88ccd327335a9f7d)', Time: '2021-04-08T09:17:58-07:00', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '8b3015f7-88f3-4494-b66c-14de47f021fb'	System	08 Apr 2021 16:19:12
User entered 'No (N)'	System	08 Apr 2021 16:19:12

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[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 (88ccd327335a9f7d)', Time: '2021-04-08T09:18:02-07:00', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '8b3015f7-88f3-4494-b66c-14de47f021fb' User entered 'No (N)'	System	08 Apr 2021 16:19:12
	System	08 Apr 2021 16:19:12

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[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 (88ccd327335a9f7d)', Time: '2021-04-08T09:18:11-07:00', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '8b3015f7-88f3-4494-b66c-14de47f021fb' User entered 'Yes (Y)'	System	08 Apr 2021 16:19:12
	System	08 Apr 2021 16:19:12



**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Please 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 (88ccd327335a9f7d)', Time: '2021-04-08T09:18:20-07:00', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '8b3015f7-88f3-4494-b66c-14de47f021fb'	System	08 Apr 2021 16:19:12
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	08 Apr 2021 16:19:12

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88ccd327335a9f7d)', Time: '2021-04-08T09:18:23-07:00', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '8b3015f7-88f3-4494-b66c-14de47f021fb'	System	08 Apr 2021 16:19:12
User entered '08 Apr 2021 09:18:23'	System	08 Apr 2021 16:19:12

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[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 (88ccd327335a9f7d)', Time: '2021-04-15T08:45:45-07:00', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '492e0383-4d34-4474-a59e-c668e66a9630'	System	15 Apr 2021 15:45:52
User entered 'No (N)'	System	15 Apr 2021 15:45:52

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

Have you been exposed to someone with 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 (88ccd327335a9f7d)', Time: '2021-04-15T08:45:47-07:00', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '492e0383-4d34-4474-a59e-c668e66a9630'	System	15 Apr 2021 15:45:52
User entered 'No (N)'	System	15 Apr 2021 15:45:52

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88ccd327335a9f7d)', Time: '2021-04-15T08:45:50-07:00', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '492e0383-4d34-4474-a59e-c668e66a9630'	System	15 Apr 2021 15:45:52
User entered '15 Apr 2021 08:45:50'	System	15 Apr 2021 15:45:52



**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[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 (88ccd327335a9f7d)', Time: '2021-04-24T14:45:46-07:00', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'ce7d24d6-971c-4587-8784-1d3a2031c259'	System	24 Apr 2021 21:45:54
User entered 'No (N)'	System	24 Apr 2021 21:45:54

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

Have you been exposed to someone with 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 (88ccd327335a9f7d)', Time: '2021-04-24T14:45:48-07:00', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'ce7d24d6-971c-4587-8784-1d3a2031c259'	System	24 Apr 2021 21:45:54
User entered 'No (N)'	System	24 Apr 2021 21:45:54

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88ccd327335a9f7d)', Time: '2021-04-24T14:45:51-07:00', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: 'ce7d24d6-971c-4587-8784-1d3a2031c259'	System	24 Apr 2021 21:45:54
User entered '24 Apr 2021 14:45:51'	System	24 Apr 2021 21:45:54

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 03:56:16



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 03:56:16

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 03:56:16



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 03:56:16



**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 03:56:16



**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 03:56:16



**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 03:56:16



**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 03:56:16



**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 03:56:16



**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 03:56:16



**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 03:56:16



**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 03:56:16



**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 03:56:16



**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 03:56:16



**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 03:56:16



**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 03:56:16



**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 03:56:16



**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 03:56:16



**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 03:56:16



**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 03:56:16



**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 03:56:16



**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 03:56:16



**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 03:56:16



**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 03:56:16



**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 03:56:16



**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 03:56:16



**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 03:56:16



**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 03:56:16



**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 03:56:16



**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 03:56:16



**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 03:56:16

**US3462116**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:56:16
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 03:56:16

US3462116

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:41:32

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:43:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88ccd327335a9f7d)', Time: '2021-03-01T15:08:07-08:00', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '29e2de61-9e4e-4c62-8d83-4138166d36dd'	System	01 Mar 2021 23:13:07
User entered 'No (N)'	System	01 Mar 2021 23:13:07



**US3462116**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 17:41:32**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:43:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88ccd327335a9f7d)', Time: '2021-03-01T15:08:12-08:00', User OID: 'PatientReportedOutcome (US3462116)', ODM File OID: '29e2de61-9e4e-4c62-8d83-4138166d36dd'	System	01 Mar 2021 23:13:07
User entered '01 Mar 2021 15:08:12'	System	01 Mar 2021 23:13:07

**US3462116**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:41:32**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Nov 2020 23:18:40

US3462116

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:32

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
User closed query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	18 Nov 2020 10:01:35
Query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Confirmed.' (Site from System).		17 Nov 2020 23:18:55
User opened query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	17 Nov 2020 23:18:40
User entered '05 Nov 2020'	(b) (4), (b) (6)	17 Nov 2020 23:18:40

**US3462116**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:41:32**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:18:40

US3462116

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:32

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 23:18:40

US3462116

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Nov 2020 23:19:04

**US3462116**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:41:32**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:31:31
User entered 'I'	System	17 Nov 2020 23:19:04

**US3462116**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:41:32**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Dec 2020 22:53:26



US3462116

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:32

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
User entered '08 Dec 2020'	(b) (4), (b) (6)	15 Dec 2020 22:53:26

**US3462116**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:41:32**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	15 Dec 2020 22:53:26

US3462116

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:32

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 22:53:26

US3462116

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Dec 2020 22:53:32

**US3462116**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:41:32**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:32
User entered 'I'	System	15 Dec 2020 22:53:32

**US3462116**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:41:32**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Feb 2021 20:44:30

US3462116

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:32

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
User closed query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	09 Feb 2021 14:43:02
Query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered with 'Confirmed date is correct' (Site from System).		08 Feb 2021 20:45:13
User opened query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	08 Feb 2021 20:44:30
User entered '07 Jan 2021'	(b) (4), (b) (6)	08 Feb 2021 20:44:30

**US3462116**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:41:32**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	08 Feb 2021 20:44:30



US3462116

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:32

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
User entered empty.	(b) (4), (b) (6)	08 Feb 2021 20:44:30

US3462116

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Feb 2021 20:45:19

**US3462116**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:41:32**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:32
User entered 'I'	System	08 Feb 2021 20:45:19

**US3462116**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:41:32**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Feb 2021 20:45:33

US3462116

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:32

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
User closed query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	08 Feb 2021 20:45:43
Query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	08 Feb 2021 20:45:43
User entered '08 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Feb 2021 20:45:43
User opened query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	08 Feb 2021 20:45:33
User entered '05 Feb 2021'	(b) (4), (b) (6)	08 Feb 2021 20:45:33

**US3462116**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:41:32**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	08 Feb 2021 20:45:33

US3462116

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:32

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
User entered empty.	(b) (4), (b) (6)	08 Feb 2021 20:45:33

US3462116

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Feb 2021 20:45:49



**US3462116**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:41:32**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:32
User entered 'I'	System	08 Feb 2021 20:45:49

US3462116

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:41:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:32
User closed query 'Per CDM: Vital Signs page has not been entered, please complete.' (Site from DM).		02 Apr 2021 12:33:26
Query 'Per CDM: Vital Signs page has not been entered, please complete.' answered with 'updated' (Site from DM).		01 Apr 2021 19:11:56
User opened query 'Per CDM: Vital Signs page has not been entered, please complete.' (Site from DM).		30 Mar 2021 10:33:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Mar 2021 20:27:16

US3462116

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:41:32

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:47
User closed query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4)	
Query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'per source document date is correct , unknow why it was not done during range ' (Site from System).	(b) (4), (b) (6)	04 Mar 2021 08:50:00
User opened query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).		02 Mar 2021 20:27:50
User entered '26 Feb 2021'	System	02 Mar 2021 20:27:16
	(b) (4), (b) (6)	02 Mar 2021 20:27:16

**US3462116**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:41:32**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:47
User entered 'Clinic (Clinic)'	(b) (4) (u) (4), (b) (6)	02 Mar 2021 20:27:16

**US3462116**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:41:32**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:32
User entered 'VISIT4'	System	02 Mar 2021 20:27:16

US3462116

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:32
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 21:37:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Mar 2021 19:25:08

US3462116

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:32
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 21:37:16
User entered '26 Feb 2021'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:25:08

**US3462116**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:41:32**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:32
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 21:37:16
User entered '11:14'	(b) (4), (b) (6)	31 Mar 2021 19:25:08



**US3462116**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:41:32**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:32
User entered '26 Feb 2021 11:14'	System	31 Mar 2021 19:25:08

US3462116

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:32
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 21:37:16
User entered '96.9' F	(b) (4), (b) (6)	31 Mar 2021 19:25:08

US3462116

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:32
User closed query 'Per CDM: Thank you for updating this form. Visit 4 and OL-D29 both dated 26 FEB 2021. However the route of measurement is Other-tympanic on this form which doesn't match with the route Oral at OL-D29 visit. Please review the response and update the appropriate route at both the visits. Thank you. ' (Site from DM).		06 Apr 2021 12:15:25
Query 'Per CDM: Thank you for updating this form. Visit 4 and OL-D29 both dated 26 FEB 2021. However the route of measurement is Other-tympanic on this form which doesn't match with the route Oral at OL-D29 visit. Please review the response and update the appropriate route at both the visits. Thank you. ' answered with 'Route is tympanic, OL-29 page updated.' (Site from DM).		05 Apr 2021 20:47:54
User opened query 'Per CDM: Thank you for updating this form. Visit 4 and OL-D29 both dated 26 FEB 2021. However the route of measurement is Other-tympanic on this form which doesn't match with the route Oral at OL-D29 visit. Please review the response and update the appropriate route at both the visits. Thank you. ' (Site from DM).		02 Apr 2021 12:32:13
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 21:37:16
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:25:08

US3462116

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:32
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 21:37:16
User entered 'Tympanic'	(b) (4), (b) (6)	31 Mar 2021 19:25:08

US3462116

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:32
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 21:37:16
User entered '104'	(b) (4), (b) (6)	31 Mar 2021 19:25:08

**US3462116**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:41:32**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:32
User entered 'bpm'	System	31 Mar 2021 19:25:08

US3462116

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:32

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:32
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 21:37:16
User entered '16'	(b) (4), (b) (6)	31 Mar 2021 19:25:08

US3462116

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:32
User entered 'breaths/min'	System	31 Mar 2021 19:25:08



US3462116

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:32
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 21:37:16
User entered '123'	(b) (4), (b) (6)	31 Mar 2021 19:25:08

**US3462116**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:41:32**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:32
User entered 'mmHg'	System	31 Mar 2021 19:25:08

US3462116

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:32
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 21:37:16
User entered '83'	(b) (4), (b) (6)	31 Mar 2021 19:25:08

**US3462116**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:41:32**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:32
User entered 'mmHg'	System	31 Mar 2021 19:25:08

**US3462116**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:41:32**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:32

**US3462116**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:41:32**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:32

**US3462116**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:41:32**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:27:59

**US3462116**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:41:32**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:27:59



US3462116

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:28:13

**US3462116**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:41:32**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered '26 Feb 2021'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:28:13

**US3462116**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:41:32**

**Collection time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered '12:00'	(b) (4) (o) (4), (b) (6)	02 Mar 2021 20:28:13

**US3462116**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:41:32**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:32
User entered '26 Feb 2021 12:00'	System	02 Mar 2021 20:28:13

**US3462116**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:41:32**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:28:19

**US3462116**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:41:32**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:14:32
User entered 'I'	System	02 Mar 2021 20:28:19

**US3462116**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:41:32**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 13:10:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:01:45

US3462116

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:32

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Safety Call Day 239 'Date of Contact or Contact Attempt' is less than 207 days or greater than 213 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System). User signature succeeded.	(b) (4), (b) (6)	15 Apr 2021 15:11:32
Query 'Safety Call Day 239 'Date of Contact or Contact Attempt' is less than 207 days or greater than 213 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Confirmed, date calculated from date of randomization.' (Site from System). User entered '06 Apr 2021' reason for change: Data Entry Error	Gregg Lucksinger (b) (4) (b) (4) (b) (4), (b) (6)	09 Apr 2021 13:10:25 07 Apr 2021 18:07:55 07 Apr 2021 18:07:37
User opened query 'Safety Call Day 239 'Date of Contact or Contact Attempt' is less than 207 days or greater than 213 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System). User entered '05 Apr 2021'	System (b) (4), (b) (6)	07 Apr 2021 18:01:45 07 Apr 2021 18:01:45



**US3462116**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:41:32**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 13:10:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:01:45

US3462116

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:32

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 13:10:25
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 18:01:45

US3462116

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 13:10:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:01:55

**US3462116**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:41:32**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	07 Apr 2021 18:01:55

US3462116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:41:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User closed query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab(Single): Sample dated 29-Jan-2021 is reported under OL-D1 visit in PPD Central lab, however the same is missing in EDC under Participant Decision Visit OL-D1(1).Please review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:13:26
' (Site from DM). Query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab(Single): Sample dated 29-Jan-2021 is reported under OL-D1 visit in PPD Central lab, however the same is missing in EDC under Participant Decision Visit OL-D1(1).Please review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.		24 Feb 2021 17:07:59
' answered with 'updated missing data' (Site from DM). User opened query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab(Single): Sample dated 29-Jan-2021 is reported under OL-D1 visit in PPD Central lab, however the same is missing in EDC under Participant Decision Visit OL-D1(1).Please review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.		19 Feb 2021 04:40:43
' (Site from DM). User entered 'Yes (Y)'		08 Feb 2021 20:46:09

**US3462116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:41:32**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered '29 Jan 2021'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:46:09

**US3462116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:41:32**

[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 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:46:09

**US3462116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:41:32**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User entered 'UNBLND_DECIDE'	System	08 Feb 2021 20:46:09



US3462116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:41:32

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
User entered '29 Jan 2021'	(b) (4), (b) (6)	08 Feb 2021 20:46:38

**US3462116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:41:32**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 03:47:12

US3462116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:41:32

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Feb 2021 20:46:38

**US3462116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:41:32**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 03:47:12

US3462116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:41:32

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
User entered '29 Jan 2021'	(b) (4), (b) (6)	08 Feb 2021 20:46:38

US3462116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:41:32

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:46:38

US3462116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:41:32

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	08 Feb 2021 20:46:38

US3462116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:41:32

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 20:46:38



US3462116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:41:32

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Feb 2021 20:46:38

**US3462116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:41:32**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User entered '1'	System	08 Feb 2021 20:46:38

**US3462116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:41:32**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User entered 'I'	System	08 Feb 2021 20:46:38

**US3462116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 17:41:32**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered '172' cm	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:04:42

**US3462116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 17:41:32**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered '105.7' kg	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:04:42

US3462116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:41:32

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User entered '35.72877'	System	24 Feb 2021 17:04:42
DataPoint set to visible.	System	08 Feb 2021 20:46:38

**US3462116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 17:41:32**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered '172' cm	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:04:42

US3462116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:41:32

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered '105.7' kg	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:04:42



US3462116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:41:32

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User entered '35.72877'	System	24 Feb 2021 17:04:42
DataPoint set to visible.	System	08 Feb 2021 20:46:38

**US3462116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:41:32**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User accepted default value 'Pre-Dose (PREDOSE)'		24 Feb 2021 17:04:42

**US3462116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:41:32**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:04:42

US3462116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered '29 Jan 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:04:42

**US3462116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:41:32**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered '11:55'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:04:42

**US3462116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:41:32**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User entered '29 Jan 2021 11:55'	System	24 Feb 2021 17:04:42

US3462116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User entered '97.8' F reason for change: Data Entry Error	System	24 Feb 2021 17:05:11
	(b) (4), (b) (6)	24 Feb 2021 17:05:11
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	24 Feb 2021 17:04:42
User entered '97.8' (non-conformant).	(b) (4), (b) (6)	24 Feb 2021 17:04:42

US3462116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	22 Apr 2021 22:33:05
Signature has been broken.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:42:49
User entered 'Other (Other)' reason for change: Data Entry Error		22 Apr 2021 18:42:49
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:05:11
User entered empty.		24 Feb 2021 17:04:42



US3462116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	22 Apr 2021 22:33:05
Signature has been broken.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:42:49
User entered 'TYMPANIC' reason for change: Data Entry Error		22 Apr 2021 18:42:49
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:04:42

US3462116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	24 Feb 2021 17:05:11
Query 'Data is required. Please provide.' answered by System	System	24 Feb 2021 17:05:11
data change (Site from System).		
User entered '85' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 17:05:11
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Feb 2021 17:04:42
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 17:04:42

**US3462116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:41:32**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User entered 'bpm'	System	24 Feb 2021 17:05:11
User entered empty.	System	24 Feb 2021 17:04:42

US3462116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:32

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Luck singer (b) (4)	19 Mar 2021 19:07:30
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	24 Feb 2021 17:05:11
Query 'Data is required. Please provide.' answered by System	System	24 Feb 2021 17:05:11
data change (Site from System).		
User entered '18' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 17:05:11
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Feb 2021 17:04:42
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 17:04:42

US3462116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User entered 'breaths/min'	System	24 Feb 2021 17:05:11
User entered empty.	System	24 Feb 2021 17:04:42

US3462116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	24 Feb 2021 17:05:11
Query 'Data is required. Please provide.' answered by System	System	24 Feb 2021 17:05:11
data change (Site from System).		
User entered '180' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 17:05:11
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Feb 2021 17:04:42
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 17:04:42

US3462116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User entered 'mmHg'	System	24 Feb 2021 17:05:11
User entered empty.	System	24 Feb 2021 17:04:42

US3462116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	24 Feb 2021 17:05:11
Query 'Data is required. Please provide.' answered by System	System	24 Feb 2021 17:05:11
data change (Site from System).		
User entered '90' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 17:05:11
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Feb 2021 17:04:42
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 17:04:42



US3462116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:32

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User entered 'mmHg'	System	24 Feb 2021 17:05:11
User entered empty.	System	24 Feb 2021 17:04:42

US3462116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:41:32

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered '172' cm	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:04:42

US3462116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:41:32

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered '105.7' kg	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:04:42

US3462116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:41:32

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User entered '35.72877'	System	24 Feb 2021 17:04:42
DataPoint set to visible.	System	08 Feb 2021 20:46:38

**US3462116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:41:32**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User accepted default value 'Post-Dose (POSTDOSE)'		24 Feb 2021 17:06:15

US3462116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:06:15

**US3462116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:41:32**

**Date of assessment (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered '29 Jan 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:06:15

**US3462116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:41:32**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered '13:20'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:06:15



**US3462116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:41:32**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User entered '29 Jan 2021 13:20'	System	24 Feb 2021 17:06:15

US3462116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered '98.1' F	(b) (4) (o) (4), (b) (6)	24 Feb 2021 17:06:15

US3462116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	22 Apr 2021 22:33:05
Signature has been broken.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:42:49
User entered 'Other (Other)' reason for change: Data Entry Error		22 Apr 2021 18:42:49
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:06:15

US3462116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	22 Apr 2021 22:33:05
Signature has been broken.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:42:49
User entered 'TYMPANIC' reason for change: Data Entry Error		22 Apr 2021 18:42:49
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:06:15

**US3462116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:41:32**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered '87'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:06:15

**US3462116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:41:32**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User entered 'bpm'	System	24 Feb 2021 17:06:15

US3462116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:32

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered '14'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:06:15

US3462116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User entered 'breaths/min'	System	24 Feb 2021 17:06:15



US3462116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered '124'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:06:15

**US3462116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:41:32**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User entered 'mmHg'	System	24 Feb 2021 17:06:15

**US3462116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:41:32**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered '73'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:06:15

**US3462116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:41:32**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User entered 'mmHg'	System	24 Feb 2021 17:06:15

US3462116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:41:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:06:35

US3462116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:41:32

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:06:35

US3462116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:41:32

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:06:50

**US3462116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:41:32**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:06:50



US3462116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:41:32

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)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:06:50

**US3462116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:41:32**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User entered 'mRNA-1273'	System	24 Feb 2021 17:06:50
DataPoint set to visible.	System	08 Feb 2021 20:46:38

US3462116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:41:32

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered '29 Jan 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:06:50

**US3462116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:41:32**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered '12:50'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:06:50

**US3462116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:41:32**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User entered '29 Jan 2021 12:50'	System	24 Feb 2021 17:06:50

**US3462116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:41:32**

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered 'Right Arm (RIGHT ARM)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:06:50

US3462116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:41:32

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User entered 'ONCE'	System	24 Feb 2021 17:06:50

**US3462116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:41:32**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User entered 'INTRAMUSCULAR'	System	24 Feb 2021 17:06:50



**US3462116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:41:32**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:07:08

US3462116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:32

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered '29 Jan 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:07:08

**US3462116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:41:32**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered '11:48'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:07:08

**US3462116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:41:32**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User entered '29 Jan 2021 11:48'	System	24 Feb 2021 17:07:08

**US3462116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:41:32**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:07:17

**US3462116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:41:32**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered '29 Jan 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:07:17

**US3462116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:41:32**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered '11:37'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:07:17

**US3462116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:41:32**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User entered '29 Jan 2021 11:37'	System	24 Feb 2021 17:07:17



**US3462116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:41:32**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:07:22

**US3462116**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:41:32**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User entered 'I'	System	24 Feb 2021 17:07:22

**US3462116**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:41:32**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:25:55

**US3462116**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:41:32**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:25:55

**US3462116**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:41:32**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:25:55

**US3462116**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:41:32**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:25:55

**US3462116**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:41:32**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:26:06

**US3462116**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:41:32**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User entered 'I'	System	02 Mar 2021 20:26:06



**US3462116**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:41:32**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User entered 'I'	System	02 Mar 2021 20:26:06
DataPoint set to visible.	System	02 Mar 2021 20:26:06

**US3462116**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:41:32**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:28:40

**US3462116**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:41:32**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered '26 Feb 2021'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:28:40

**US3462116**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:41:32**

[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 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:28:40

**US3462116**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:41:32**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User entered 'OLD29'	System	02 Mar 2021 20:28:40

**US3462116**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:41:32**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User accepted default value 'Pre-Dose (PREDOSE)'		02 Mar 2021 20:29:20

**US3462116**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:41:32**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:29:20

**US3462116**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:41:32**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered '26 Feb 2021'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:29:20



**US3462116**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:41:32**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered '11:14'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:29:20

**US3462116**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:41:32**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User entered '26 Feb 2021 11:14'	System	02 Mar 2021 20:29:20

US3462116

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered '96.9' F	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:29:20

US3462116

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 21:21:45
Signature has been broken.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 20:46:27
User entered 'Other (Other)' reason for change: Data Entry Error		05 Apr 2021 20:46:27
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:29:20

US3462116

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 21:21:45
Signature has been broken.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 20:46:27
User entered 'Tympanic' reason for change: Data Entry Error		05 Apr 2021 20:46:27
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:29:20

**US3462116**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:41:32**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered '104'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:29:20

**US3462116**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:41:32**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User entered 'bpm'	System	02 Mar 2021 20:29:20

US3462116

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:32

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered '16'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:29:20



US3462116

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User entered 'breaths/min'	System	02 Mar 2021 20:29:20

**US3462116**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:41:32**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered '123'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:29:20

**US3462116**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:41:32**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User entered 'mmHg'	System	02 Mar 2021 20:29:20

**US3462116**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:41:32**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered '83'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:29:20

**US3462116**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:41:32**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User entered 'mmHg'	System	02 Mar 2021 20:29:20

**US3462116**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:41:32**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User accepted default value 'Post-Dose (POSTDOSE)'		02 Mar 2021 20:31:34

**US3462116**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:41:32**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:34

US3462116

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered '26 Feb 2021'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:34



**US3462116**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:41:32**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered '12:24'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:34

**US3462116**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:41:32**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User entered '26 Feb 2021 12:24'	System	02 Mar 2021 20:31:34

US3462116

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered '97.1' F	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:34

US3462116

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 21:21:45
Signature has been broken.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 20:46:27
User entered 'Other (Other)' reason for change: Data Entry Error		05 Apr 2021 20:46:27
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:34

US3462116

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 21:21:45
Signature has been broken.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 20:46:27
User entered 'Tympanic' reason for change: Data Entry Error		05 Apr 2021 20:46:27
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:34

**US3462116**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:41:32**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered '100'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:34

**US3462116**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:41:32**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User entered 'bpm'	System	02 Mar 2021 20:31:34

US3462116

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:32

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered '16'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:34



**US3462116**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:41:32**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User entered 'breaths/min'	System	02 Mar 2021 20:31:34

US3462116

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered '123'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:34

**US3462116**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:41:32**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User entered 'mmHg'	System	02 Mar 2021 20:31:34

**US3462116**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:41:32**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered '68'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:34

**US3462116**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:41:32**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User entered 'mmHg'	System	02 Mar 2021 20:31:34

**US3462116**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:41:32**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:49

**US3462116**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:41:32**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:31:49

**US3462116**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:41:32**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:32:21



**US3462116**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:41:32**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:32:21

US3462116

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:41:32

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)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:32:21

**US3462116**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:41:32**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User entered 'mRNA-1273'	System	02 Mar 2021 20:32:21
DataPoint set to visible.	System	02 Mar 2021 20:26:06

**US3462116**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:41:32**

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered '26 Feb 2021'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:32:21

**US3462116**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:41:32**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered '11:53'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:32:21

**US3462116**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:41:32**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User entered '26 Feb 2021 11:53'	System	02 Mar 2021 20:32:21

**US3462116**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:41:32**

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered 'Right Arm (RIGHT ARM)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:32:21

US3462116

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:41:32

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User entered 'ONCE'	System	02 Mar 2021 20:32:21



**US3462116**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:41:32**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User entered 'INTRAMUSCULAR'	System	02 Mar 2021 20:32:21

**US3462116**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:41:32**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:40:25

**US3462116**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:41:32**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User entered 'I'	System	02 Mar 2021 20:40:25

**US3462116**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:41:32**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:04:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:48:04

**US3462116**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:41:32**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:04:55
User entered '05 Mar 2021'	(b) (4), (b) (6)	30 Mar 2021 18:48:04

**US3462116**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:41:32**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:04:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:48:04

**US3462116**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:41:32**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:04:55
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:48:04

**US3462116**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:41:32**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 00:04:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:48:48



**US3462116**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:41:32**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:53:53
User entered 'I'	System	30 Mar 2021 18:48:48

US3462116

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:41:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 13:10:25
Signature has been broken.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:59:55
User entered 'Yes (Y)' reason for change: Data Entry Error		08 Apr 2021 21:59:55
User closed query 'Data is required. Please complete.' (Site from System).		02 Apr 2021 10:44:45
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:05:26
Query 'Data is required. Please complete.' answered with 'added in error' (Site from System).	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:59:03
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Apr 2021 16:58:50
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	01 Apr 2021 16:58:50
User entered 'Yes (Y)'		01 Apr 2021 16:57:24

US3462116

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:41:32

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 13:10:25
Signature has been broken.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:59:55
User entered '08 Apr 2021' reason for change: Data Entry Error		08 Apr 2021 21:59:55
User closed query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' (Site from System).		02 Apr 2021 10:44:47
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:05:26
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:58:50
Query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' answered with 'Per PI okay ' (Site from System).		01 Apr 2021 16:57:33
User opened query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' (Site from System).	System	01 Apr 2021 16:57:24
User entered '05 Mar 2021'	(b) (4), (b) (6)	01 Apr 2021 16:57:24

US3462116

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:41:32

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 13:10:25
Signature has been broken.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:59:55
User entered 'Clinic (Clinic)' reason for change: Data Entry Error		08 Apr 2021 21:59:55
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:05:26
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:58:50
User entered 'Clinic (Clinic)'		01 Apr 2021 16:57:24

**US3462116**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:41:32**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	08 Apr 2021 21:59:55
User entered empty.	System	01 Apr 2021 16:58:50
User entered 'OLD57'	System	01 Apr 2021 16:57:24

US3462116

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 13:10:25
Signature has been broken.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 22:00:02
User entered 'No (N)' reason for change: Data Entry Error		08 Apr 2021 22:00:02
User closed query 'Data is required. Please complete.' (Site from System).		02 Apr 2021 10:45:02
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:05:26
Query 'Data is required. Please complete.' answered with 'added in error' (Site from System).	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:59:16
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Apr 2021 16:59:09
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	01 Apr 2021 16:59:09
User entered 'No (N)'		01 Apr 2021 16:57:39

US3462116

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:05:26
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:57:39

**US3462116**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:41:32**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:05:26
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:57:39



**US3462116**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:41:32**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 16:57:39

US3462116

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:32

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:05:26
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:57:39

**US3462116**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:41:32**

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:05:26
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:57:39

**US3462116**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:41:32**

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:05:26
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:57:39

**US3462116**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:41:32**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:05:26
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:57:39

**US3462116**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:41:32**

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 16:57:39

US3462116

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:32

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:05:26
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:57:39

**US3462116**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:41:32**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 16:57:39



US3462116

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:05:26
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:57:39

**US3462116**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:41:32**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 16:57:39

US3462116

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:05:26
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:57:39

**US3462116**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:41:32**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 16:57:39

US3462116

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:41:32

Was the physical examination performed?

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 13:10:25
Signature has been broken.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 22:00:07
User entered 'No (N)' reason for change: Data Entry Error		08 Apr 2021 22:00:07
User closed query 'Data is required. Please complete.' (Site from System).		02 Apr 2021 10:44:51
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:05:26
Query 'Data is required. Please complete.' answered with 'added in error' (Site from System).	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:59:28
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Apr 2021 16:59:20
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	01 Apr 2021 16:59:20
User entered 'No (N)'		01 Apr 2021 16:57:43

US3462116

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:41:32

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:05:26
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:57:43

US3462116

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 13:10:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 22:00:23

US3462116

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:32

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 13:10:25
User entered '08 Apr 2021'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 22:00:23



**US3462116**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:41:32**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 13:10:25
User entered '14:04'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 22:00:23

**US3462116**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:41:32**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '08 Apr 2021 14:04'	System	08 Apr 2021 22:00:23

US3462116

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:41:32

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:27:56
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:48:17
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	10 Sep 2020 22:17:17

US3462116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:32

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:20:26
Reviewed for Safety.		12 Sep 2020 15:31:27
User entered 'USA-US093-2020-mRNA-1273-P301000003'	System	12 Sep 2020 15:31:11
User entered 'New'	(b) (4), (b) (6)	12 Sep 2020 15:31:11

US3462116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:32

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:20:26
User coded data point as SOC: Cardiac disorders, HLGT: Heart failures, HLT: Heart failures NEC, PT: Cardiac failure congestive, LLT: Congestive heart failure - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 22:25:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 22:25:51
Data point term sent to Coder	System	10 Sep 2020 22:24:50
User entered 'Congestive Heart Failure'	Danuel Hamlin (b) (4)	10 Sep 2020 22:23:53

**US3462116**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:41:32**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)  	10 Sep 2020 22:23:53

**US3462116**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:41:32**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered 'No (N)'	Danuel Hamlin (b) (4) [REDACTED] [REDACTED]	10 Sep 2020 22:23:53

US3462116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:32

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered 'No (N)'	Danuel Hamlin (b) (4) [REDACTED] [REDACTED]	10 Sep 2020 22:23:53



US3462116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:20:26
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	16 Sep 2020 23:51:54
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	14 Sep 2020 21:16:23
User entered '03 Sep 2020'	Danuel Hamlin (b) (4)	10 Sep 2020 22:23:53

US3462116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:32

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:03:00
		05 Nov 2020 23:20:26
Query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' answered with 'Confirmed. Time is correct' (Site from System).	Danuel Hamlin (b) (4)	04 Nov 2020 15:36:35
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	10 Sep 2020 22:23:53
User entered '08:00'	Danuel Hamlin (b) (4)	10 Sep 2020 22:23:53

**US3462116**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:41:32**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 08:00'	System	10 Sep 2020 22:23:53

**US3462116**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:41:32**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered 'No (N)'	Danuel Hamlin (b) (4) [REDACTED] [REDACTED]	10 Sep 2020 22:23:53

US3462116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:32

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered '09 Sep 2020'	Danuel Hamlin (b) (4) [REDACTED] [REDACTED]	10 Sep 2020 22:23:53

US3462116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:32

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
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). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:03:05
		05 Nov 2020 23:20:26
Query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' answered with 'Confirmed. Time is correct' (Site from System).	Danuel Hamlin (b) (4)	04 Nov 2020 15:36:45
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	10 Sep 2020 22:23:53
User entered '17:00'	Danuel Hamlin (b) (4)	10 Sep 2020 22:23:53

**US3462116**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:41:32**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 17:00'	System	10 Sep 2020 22:23:53

**US3462116**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:41:32**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered 'Grade 4 (Grade 4)'	Danuel Hamlin (b) (4) [REDACTED] [REDACTED]	10 Sep 2020 22:23:53



US3462116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:32

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered 'Yes (Y)'	Danuel Hamlin (b) (4) [REDACTED] [REDACTED]	10 Sep 2020 22:23:53

**US3462116**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:41:32**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered '0'	Danuel Hamlin (b) (4)	10 Sep 2020 22:23:53

US3462116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:32

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered '0'	Danuel Hamlin (b) (4)	10 Sep 2020 22:23:53

**US3462116**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:41:32**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered 'I'	Danuel Hamlin (b) (4) [REDACTED] [REDACTED]	10 Sep 2020 22:23:53

US3462116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:32

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered '05 Sep 2020' reason for change: Data Entry Error	Danuel Hamlin (b) (4)	05 Nov 2020 19:57:42
User entered '04 Sep 2020'	Danuel Hamlin (b) (4)	10 Sep 2020 22:23:53

US3462116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:32

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered '09 Sep 2020'	Danuel Hamlin (b) (4) [REDACTED] [REDACTED]	10 Sep 2020 22:23:53

**US3462116**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:41:32**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered 'No (N)'	Danuel Hamlin (b) (4) [REDACTED] [REDACTED]	10 Sep 2020 22:23:53

US3462116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:32

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered empty.	Danuel Hamlin (b) (4) [REDACTED] [REDACTED]	10 Sep 2020 22:23:53



US3462116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered '0'	Danuel Hamlin (b) (4) [REDACTED] [REDACTED]	10 Sep 2020 22:23:53

US3462116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered '0'	Danuel Hamlin (b) (4) [REDACTED] [REDACTED]	10 Sep 2020 22:23:53

US3462116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:32

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered '0'	Danuel Hamlin (b) (4) [REDACTED] [REDACTED]	10 Sep 2020 22:23:53

US3462116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:32

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered 'Not Related (NOT RELATED)'	Danuel Hamlin (b) (4) [REDACTED] [REDACTED]	10 Sep 2020 22:23:53

US3462116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:32

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered 'Not Related (NOT RELATED)'	Danuel Hamlin (b) (4) [REDACTED] [REDACTED]	10 Sep 2020 22:23:53

**US3462116**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:41:32**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered 'None (NONE)'	Danuel Hamlin (b) (4) [REDACTED] [REDACTED]	10 Sep 2020 22:23:53

US3462116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:32

None

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered '0'	Danuel Hamlin (b) (4) [REDACTED] [REDACTED]	10 Sep 2020 22:23:53

US3462116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:32

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User closed query 'Per DM CLR - RQ: Site's response noted. However, there is CM with indication of "CONGESTIVE HEART FAILURE". Note that AE term and CM indication should be verbatim. Please review and add a Con Medication a appropriate or update action taken.' (Site from DM). Query 'Per DM CLR - RQ: Site's response noted. However, there is CM with indication of "CONGESTIVE HEART FAILURE". Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken.' answered with 'updated con meds' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Mar 2021 08:53:40
User opened query 'Per DM CLR - RQ: Site's response noted. However, there is CM with indication of "CONGESTIVE HEART FAILURE". Note that AE term and CM indication should be verbatim. Please review and add a Con Medication a appropriate or update action taken.' (Site from DM).		02 Mar 2021 20:17:10
User closed query 'Per CDM re-query: There is no Con med with the indication "CONGESTIVE HEART FAILURE" which matches this AE. Please update the indication term to match the AE else update the Other action taken as appropriate. ' (Site from DM).		01 Mar 2021 09:58:59
Query 'Per CDM re-query: There is no Con med with the indication "CONGESTIVE HEART FAILURE" which matches this AE. Please update the indication term to match the AE else update the Other action taken as appropriate. ' answered with 'Added medication to con meds for this AE ' (Site from DM).		01 Mar 2021 09:58:59
User opened query 'Per CDM re-query: There is no Con med with the indication "CONGESTIVE HEART FAILURE" which matches this AE. Please update the indication term to match the AE else update the Other action taken as appropriate. ' (Site from DM).		24 Feb 2021 16:54:52
DataPoint Verified.		16 Feb 2021 10:16:23
		05 Nov 2020 23:20:26



US3462116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:32

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered 'I'	Danuel Hamlin (b) (4)	10 Sep 2020 22:23:53

US3462116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:32

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User closed query 'Per DM CLR: Other Action Take = ConProc. However, the recorded procedure that match this AE were Diagnostic procedures rather than a Therapeutic procedures. Please update to record the therapeutic procedure for this AE as appropriate. Otherwise, clarify.' (Site from DM). Query 'Per DM CLR: Other Action Taken = ConProc. However, the recorded procedure that match this AE were Diagnostic procedures rather than a Therapeutic procedures. Please update to record the therapeutic procedure for this AE as appropriate. Otherwise, clarify.' answered with 'Corrected' (Site from DM). DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 10:14:39
		15 Feb 2021 21:49:35
		15 Feb 2021 21:45:16
User entered '0' reason for change: Data Entry Error		15 Feb 2021 21:45:16
User opened query 'Per DM CLR: Other Action Taken = ConProc. However, the recorded procedure that match this AE were Diagnostic procedures rather than a Therapeutic procedures. Please update to record the therapeutic procedure for this AE as appropriate. Otherwise, clarify.' (Site from DM). DataPoint Verified.		29 Nov 2020 11:44:48
		05 Nov 2020 23:20:26
User entered '1'	Danuel Hamlin (b) (4)	10 Sep 2020 22:23:53

**US3462116**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:41:32**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Danuel Hamlin (b) (4) [REDACTED] [REDACTED]	10 Sep 2020 22:23:53

US3462116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:32

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered empty.	Danuel Hamlin (b) (4)  	10 Sep 2020 22:23:53

US3462116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:32

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User closed query 'PV Query: Please complete the mRNA-1273 for the subject's unblinding visit, when available.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:19:18
Query 'PV Query: Please complete the mRNA-1273 for the subject's unblinding visit, when available.' answered with 'updated data' (Site from Safety).		24 Feb 2021 16:54:34
User opened query 'PV Query: Please complete the mRNA-1273 for the subject's unblinding visit, when available.' (Site from Safety).		23 Feb 2021 18:36:35
User closed query 'Per DM CLR: Narrative indicates that the subject had a history of Methamphetamine abuse in 19993-2003. However, there is no corresponding MH record that match the information Please update to record the corresponding MH as applicable. Otherwise, clarify.' (Site from DM).		16 Feb 2021 10:17:24
Query 'Per DM CLR: Narrative indicates that the subject had a history of Methamphetamine abuse in 19993-2003. However, there is no corresponding MH record that match the information. Please update to record the corresponding MH as applicable. Otherwise, clarify.' answered with 'Updated' (Site from DM).		15 Feb 2021 21:49:43
User closed query 'PV Query: Please confirm if concomitant medication indications of "type II diabetes" and "exertional bronchospasm" should be added as medical history.' (Site from Safety).		30 Nov 2020 18:55:06
User opened query 'Per DM CLR: Narrative indicates that the subject had a history of Methamphetamine abuse in 19993-2003. However, there is no corresponding MH record that match the information. Please update to record the corresponding MH as applicable. Otherwise, clarify.' (Site from DM).		29 Nov 2020 11:45:00
Query 'PV Query: Please confirm if concomitant medication indications of "type II diabetes" and "exertional bronchospasm" should be added as medical history.' answered with 'Added' (Site from Safety).	Danuel Hamlin (b) (4)	25 Nov 2020 02:23:21

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:32

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please confirm if concomitant medication indications of "type II diabetes" and "exertional bronchospasm" should be added as medical history.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 15:55:48
User closed query 'Per DM CLR: SAE Narrative contains medications and procedures. Please make sure that these information are recorded in their respective eCRFs. Otherwise, clarify the inconsistencies.		13 Nov 2020 15:13:19
' (Site from DM).		
User closed query 'PV Query: Please provide echocardiogram results.' (Site from Safety).		06 Nov 2020 19:12:29
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.' (Site from Safety).		06 Nov 2020 19:12:22
DataPoint Verified.		05 Nov 2020 23:20:26
Query 'PV Query: Please provide echocardiogram results.' answered with 'Echocardiogram apparently showed generalized cardiomyopathy and low ejection fraction, with LVEF of 30%. ' (Site from Safety).	Danuel Hamlin (b) (4)	05 Nov 2020 20:14:53
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'COVID-19 PCR test was negative done on about 05SEP2020. ' (Site from Safety).	Danuel Hamlin (b) (4)	05 Nov 2020 20:14:20

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:32

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PATIENT IS 43 YEAR OLD WOMAN WITH SOCIAL RISK FOR COVID-19. SHE CONSENTED AND RANDOMIZED ON 11AUG2020 AND TOLERATED DOSE 1 UNEVENTFULLY. SHE DEVELOPED NEW ONSET INCREASED DYSPNEA AND FLUID RETENTION THAT BECAME CLINICALLY BOTHERSOME ON 08:00 ON 03SEP2020. SHE WENT TO ROGUE REGIONAL MEDICAL CENTER IN MEDFORD, OR AT APPROXIMATELY 09:00 ON 04SEP2020, AND WAS ADMITTED FOR NEW ONSET CONGESTIVE HEART FAILURE (CHF). CHF WAS CONFIRMED ON CHEST X-RAY AND ECHOCARDIOGRAM, AND OTHER HEART DISEASE WAS RULED WITH ANGIOGRAM AND CHEST CT. PATIENT WAS DIURESED WITH FUROSEMIDE AND RECOVERED FULLY. SHE WAS DISCHARGED TO HOME ON 09SEP2020 AT ABOUT 17:00 ON NEW ORAL DIURETIC MEDICATIONS TO PREVENT CHF. ALL HISTORY FROM PHONE CALL TO PATIENT ON 09SEP2020 AT 18:30. WE ARE REPORTING THIS SAE TODAY. SAE report updated 05NOV2020 based on hospital discharge summary. DC summary confirms admit date was 05SEP2020 and DC date 09SEP2020. Primary diagnosis was acute CHF that improved after 2 liters diuresis with furosemide. Echo confirmed low LVEF of 30% confirming systolic CHF.   Subject also had a left heart catheterisation test performed which showed normal coronary arteries. Family history was positive for (b) (6) and (b) (6) (b) (6) both dying in 40s with possible familial cardiomyopathy and CHF. Subject also had remote history of methamphetamine abuse 1993-2003 that may have contributed to cardiomyopathy. Therefore, patient seems to have a previously undiagnosed familial cardiomyopathy which may be do to A) history of CHF in (b) (6) and (b) (6), B) weight lifting and methamphetamine abuse as teenager and young	Danuel Hamlin (b) (4)	05 Nov 2020 20:13:49

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:32

[Narrative](#)

Audit	User	Time (GMT)
adult, and C) patient also seems to have borderline diabetes type II that may contribute to cardiomyopathy. She was discharged to home on new meds for cardiomyopathy including 5 medications, and with follow-up with cardiologist planned in 2-3 months. SAE is updated today with this information from hospital records.' reason for change: New Information		
Query 'Per DM CLR: SAE Narrative contains medications and procedures. Please make sure that these information are recorded in their respective eCRFs. Otherwise, clarify the inconsistencies. ' answered with 'Added' (Site from DM).	Danuel Hamlin (b) (4)	04 Nov 2020 15:38:09
User opened query 'Per DM CLR: SAE Narrative contains medications and procedures. Please make sure that these information are recorded in their respective eCRFs. Otherwise, clarify the inconsistencies. ' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 02:34:05
User opened query 'PV Query: Please provide echocardiogram results.' (Site from Safety).		18 Sep 2020 13:43:46
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).		18 Sep 2020 13:43:34



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:32

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Patient is 43 year old woman with social risk for COVID-19. She consented and randomized on 11AUG2020 and tolerated Dose 1 uneventfully. She developed new onset increased dyspnea and fluid retention that became clinically bothersome on 08:00 on 03SEP2020. She went to Rogue Regional Medical Center in Medford, OR at approximately 09:00 on 04SEP2020, and was admitted for new onset congestive heart failure (CHF). CHF was confirmed on Chest X-ray and echocardiogram, and other heart disease was ruled with angiogram and chest CT. Patient was diuresed with furosemide and recovered fully. She was discharged to home on 09SEP2020 at about 17:00 on new oral diuretic medications to prevent CHF. All history from phone call to patient on 09SEP2020 at 18:30. We are reporting this SAE today.'	Danuel Hamlin (b) (4) [REDACTED] [REDACTED]	10 Sep 2020 22:23:53

**US3462116**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:41:32**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	10 Sep 2020 22:23:53

**US3462116**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:41:32**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	10 Sep 2020 22:23:53

**US3462116**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:41:32**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	10 Sep 2020 22:23:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:32

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User closed query 'Per DM CLR: Please review this record as this was noted as the patients Family History rather than as an AE. Please verify if this would be more appropriately recorded on the MH eCRF page. Please update to move entry to the MH eCRF page as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:16:25
Query 'Per DM CLR: Please review this record as this was noted as the patients Family History rather than as an AE. Please verify if this would be more appropriately recorded on the MH eCRF page. Please update to move entry to the MH eCRF page as appropriate. Otherwise, clarify.' answered with 'adde to medical history' (Site from DM).		24 Feb 2021 17:01:21
User opened query 'Per DM CLR: Please review this record as this was noted as the patients Family History rather than as an AE. Please verify if this would be more appropriately recorded on the MH eCRF page. Please update to move entry to the MH eCRF page as appropriate. Otherwise, clarify.' (Site from DM).		29 Nov 2020 11:45:31
DataPoint Verified.		05 Nov 2020 23:20:26
User coded data point as SOC: Cardiac disorders, HLGT: Myocardial disorders, HLT: Cardiomyopathies, PT: Cardiomyopathy, LLT: Cardiomyopathy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 23:16:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 23:16:33
Data point term sent to Coder	System	05 Nov 2020 20:17:55
User entered 'Familial Cardiomyopathy'	Danuel Hamlin (b) (4)	05 Nov 2020 20:17:25

**US3462116**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:41:32**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)  	05 Nov 2020 20:17:25

**US3462116**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:41:32**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered 'No (N)'	Danuel Hamlin (b) (4)  	05 Nov 2020 20:17:25

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:32

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered 'No (N)'	Danuel Hamlin (b) (4)  	05 Nov 2020 20:17:25



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered '05 Sep 2020'	Danuel Hamlin (b) (4)  	05 Nov 2020 20:17:25

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:32

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User closed query 'Per CDM: Per previous query, start time is not required for this AE as it did not occur within 24 hours of receiving Investigational Product. Please delete entry for start time.' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Dec 2020 16:12:11
Query 'Per CDM: Per previous query, start time is not required for this AE as it did not occur within 24 hours of receiving Investigational Product. Please delete entry for start time.' answered with 'Deleted' (Site from DM).	Danuel Hamlin (b) (4)	25 Nov 2020 02:26:35
DataPoint Un-verified.	Danuel Hamlin (b) (4)	25 Nov 2020 02:26:27
User entered empty; reason for change Data Entry Error	Danuel Hamlin (b) (4)	25 Nov 2020 02:26:27
User opened query 'Per CDM: Per previous query, start time is not required for this AE as it did not occur within 24 hours of receiving Investigational Product. Please delete entry for start time.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 15:14:31
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).		13 Nov 2020 15:13:44
DataPoint Verified.		05 Nov 2020 23:20:26
Query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' answered with 'Confirmed.' (Site from System).	Danuel Hamlin (b) (4)	05 Nov 2020 20:17:35
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	05 Nov 2020 20:17:25
User entered '12:00'	Danuel Hamlin (b) (4)	05 Nov 2020 20:17:25

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:41:32**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Nov 2020 02:26:27
User entered '05 Sep 2020 12:00'	System	05 Nov 2020 20:17:25

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:41:32**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)  	05 Nov 2020 20:17:25

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Folder: Adverse Events

Form: Adverse Events (2)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered empty.	Danuel Hamlin (b) (4) [REDACTED] [REDACTED]	05 Nov 2020 20:17:25

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:41:32**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered empty.	Danuel Hamlin (b) (4)  	05 Nov 2020 20:17:25

**US3462116**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:41:32**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 20:17:25

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Folder: Adverse Events

Form: Adverse Events (2)

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Danuel Hamlin (b) (4)  	05 Nov 2020 20:17:25



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Folder: Adverse Events

Form: Adverse Events (2)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered 'No (N)'	Danuel Hamlin (b) (4)  	05 Nov 2020 20:17:25

**US3462116**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:41:32**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered '0'	Danuel Hamlin (b) (4)  	05 Nov 2020 20:17:25

**US3462116**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:41:32**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered '0'	Danuel Hamlin (b) (4)	05 Nov 2020 20:17:25

**US3462116**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:41:32**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered '0'	Danuel Hamlin (b) (4)  	05 Nov 2020 20:17:25

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:32

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered empty.	Danuel Hamlin (b) (4) [REDACTED] [REDACTED]	05 Nov 2020 20:17:25

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:32

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered empty.	Danuel Hamlin (b) (4) [REDACTED] [REDACTED]	05 Nov 2020 20:17:25

**US3462116**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:41:32**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered empty.	Danuel Hamlin (b) (4) [REDACTED] [REDACTED]	05 Nov 2020 20:17:25

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered empty.	Danuel Hamlin (b) (4) [REDACTED] [REDACTED]	05 Nov 2020 20:17:25



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Folder: Adverse Events

Form: Adverse Events (2)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered '0'	Danuel Hamlin (b) (4) [REDACTED] [REDACTED]	05 Nov 2020 20:17:25

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Folder: Adverse Events

Form: Adverse Events (2)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered '0'	Danuel Hamlin (b) (4)  	05 Nov 2020 20:17:25

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Folder: Adverse Events

Form: Adverse Events (2)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered '0'	Danuel Hamlin (b) (4)  	05 Nov 2020 20:17:25

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Folder: Adverse Events

Form: Adverse Events (2)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered 'Not Related (NOT RELATED)'	Danuel Hamlin (b) (4) [REDACTED] [REDACTED]	05 Nov 2020 20:17:25

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:32

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User closed query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Dec 2020 16:12:34
Query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' answered with 'Corrected' (Site from DM).	Danuel Hamlin (b) (4)	25 Nov 2020 02:27:13
DataPoint Un-verified.	Danuel Hamlin (b) (4)	25 Nov 2020 02:27:08
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Danuel Hamlin (b) (4)	25 Nov 2020 02:27:08
User opened query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 10:17:06
DataPoint Verified.		05 Nov 2020 23:20:26
User entered 'Not Applicable (NOT APPLICABLE)'	Danuel Hamlin (b) (4)	05 Nov 2020 20:17:25

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Folder: Adverse Events

Form: Adverse Events (2)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered 'None (NONE)'	Danuel Hamlin (b) (4) [REDACTED] [REDACTED]	05 Nov 2020 20:17:25

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Folder: Adverse Events

Form: Adverse Events (2)

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None

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered '0'	Danuel Hamlin (b) (4)	05 Nov 2020 20:17:25

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Folder: Adverse Events

Form: Adverse Events (2)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered 'I'	Danuel Hamlin (b) (4)  	05 Nov 2020 20:17:25



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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered 'I'	Danuel Hamlin (b) (4)  	05 Nov 2020 20:17:25

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Danuel Hamlin (b) (4) [REDACTED] [REDACTED]	05 Nov 2020 20:17:25

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered empty.	Danuel Hamlin (b) (4)  	05 Nov 2020 20:17:25

**US3462116**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:41:32**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:20:26
User entered empty.	Danuel Hamlin (b) (4) [REDACTED] [REDACTED]	05 Nov 2020 20:17:25

**US3462116**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:41:32**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Nov 2020 20:17:25

**US3462116**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:41:32**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Nov 2020 20:17:25

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:41:32

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:27:56
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
User closed query 'Re-query: Please reconcile as no new medications added. As noted multiple medications not in EDC but are in SAE medical records.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:13:21
Query 'Re-query: Please reconcile as no new medications added. As noted multiple medications not in EDC but are in SAE medical records.' answered with 'Added' (Site from CRA).	Danuel Hamlin (b) (4)	25 Nov 2020 02:27:28
User opened query 'Re-query: Please reconcile as no new medications added. As noted multiple medications not in EDC but are in SAE medical records.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:58:39
User closed query 'Multiple COn-meds such as Hydrocodone not listed. Please refer to SAE medical records. Thanks ' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:58:39
Query 'Multiple COn-meds such as Hydrocodone not listed. Please refer to SAE medical records. Thanks ' answered with 'Medications have been added' (Site from CRA).	Danuel Hamlin (b) (4)	09 Nov 2020 08:41:32
User opened query 'Multiple COn-meds such as Hydrocodone not listed. Please refer to SAE medical records. Thanks ' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 23:18:29
User closed query 'Per ETRTR: Ensure updating ConMeds provided for SAE "Congestive heart failure", thanks.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 23:18:29
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:11:37
Query 'Per ETRTR: Ensure updating ConMeds provided for SAE "Congestive heart failure", thanks.' answered with 'Added' (Site from CRA).	Danuel Hamlin (b) (4)	04 Nov 2020 15:44:37
User opened query 'Per ETRTR: Ensure updating ConMeds provided for SAE "Congestive heart failure", thanks.' (Site from CRA).	(b) (4), (b) (6)	19 Sep 2020 19:02:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 02:06:06

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:41:32

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE SODIUM, PRODUCTSYNONYM: SYNTHROID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 02:08:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 02:08:17
Data point term sent to Coder	System	13 Aug 2020 02:07:19
User entered 'Synthroid'	(b) (4), (b) (6)   	13 Aug 2020 02:06:56



US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:41:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'No (N)' reason for change: Data Entry Error		09 Oct 2020 20:35:24
User entered 'Yes (Y)'		13 Aug 2020 02:06:56

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:41:32**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Hypothyroidism'		13 Aug 2020 02:06:56

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:41:32**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	05 Nov 2020 23:16:38
User entered '112'		13 Aug 2020 02:06:56

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:41:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).		29 Oct 2020 14:10:19
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'updated' (Site from DM).		24 Oct 2020 19:56:28
User entered 'ug (ug)' reason for change: Data Entry Error		24 Oct 2020 19:56:16
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).		16 Oct 2020 14:12:06
User entered 'mg (mg)'		13 Aug 2020 02:06:56

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:41:32**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.		13 Aug 2020 02:06:56

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:41:32**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'once daily (QD)'		13 Aug 2020 02:06:56

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:41:32

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.		13 Aug 2020 02:06:56

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:41:32**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Oral (ORAL)'		13 Aug 2020 02:06:56



**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:41:32**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.		13 Aug 2020 02:06:56

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:41:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		14 Aug 2020 23:51:01
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.'		13 Aug 2020 02:07:07
answered with 'confirmed' (Site from System).		
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	13 Aug 2020 02:06:56
User entered 'un UNK 2005'	(b) (4), (b) (6)	13 Aug 2020 02:06:56

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:41:32**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered '0'		13 Aug 2020 02:06:56

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:41:32**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Yes (Y)'		13 Aug 2020 02:06:56

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:41:32**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.		13 Aug 2020 02:06:56

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:41:32**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'No (N)'		13 Aug 2020 02:06:56

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:41:32**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 02:06:56

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:41:32**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 02:06:56



**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:41:32**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 02:06:56

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:41:32

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTI-PARKINSON DRUGS, ATC: DOPAMINERGIC AGENTS, ATC: DOPAMINE AGONISTS, PRODUCT: ROPINIROLE HYDROCHLORIDE, PRODUCTSYNONYM: REQUIP - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 02:09:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 02:09:19
Data point term sent to Coder	System	13 Aug 2020 02:08:22
User entered 'Requip'	(b) (4), (b) (6)  	13 Aug 2020 02:08:03

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:41:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'No (N)' reason for change: Data Entry Error		09 Oct 2020 20:35:35
User entered 'Yes (Y)'		13 Aug 2020 02:08:03

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:41:32**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Restless Leg Syndrome'		13 Aug 2020 02:08:03

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:41:32**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered '2.5'		13 Aug 2020 02:08:03

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:41:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'mg (mg)'		13 Aug 2020 02:08:03

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:41:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.		13 Aug 2020 02:08:03

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:41:32**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'twice daily (BID)'		13 Aug 2020 02:08:03



US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:41:32

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.		13 Aug 2020 02:08:03

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:41:32**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Oral (ORAL)'		13 Aug 2020 02:08:03

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:41:32**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.		13 Aug 2020 02:08:03

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:41:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		14 Aug 2020 23:51:07
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.'		13 Aug 2020 02:08:14
answered with 'confirmed' (Site from System).		
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	13 Aug 2020 02:08:03
User entered 'un UNK 2007'	(b) (4), (b) (6)	13 Aug 2020 02:08:03

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:41:32**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered '0'		13 Aug 2020 02:08:03

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:41:32**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Yes (Y)'		13 Aug 2020 02:08:03

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:41:32**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.		13 Aug 2020 02:08:03

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:41:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'No (N)'		13 Aug 2020 02:08:03



**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:41:32**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	13 Aug 2020 02:08:03

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:41:32**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 02:08:03

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:41:32**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 02:08:03

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:41:32

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
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)	13 Aug 2020 02:10:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 02:10:20
Data point term sent to Coder	System	13 Aug 2020 02:09:23
User entered 'Ibuprofen'	(b) (4), (b) (6)  (b) (4)	13 Aug 2020 02:08:54

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:41:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'No (N)' reason for change: Data Entry Error		09 Oct 2020 20:35:49
User entered 'Yes (Y)'		13 Aug 2020 02:08:54

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:41:32**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Occasional Headache'		13 Aug 2020 02:08:54

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:41:32**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered '800'		13 Aug 2020 02:08:54

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:41:32**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'mg (mg)'		13 Aug 2020 02:08:54



US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:41:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.		13 Aug 2020 02:08:54

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:41:32**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'as needed (PRN)'		13 Aug 2020 02:08:54

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:41:32

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.		13 Aug 2020 02:08:54

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:41:32**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Oral (ORAL)'		13 Aug 2020 02:08:54

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:41:32**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.		13 Aug 2020 02:08:54

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:41:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		14 Aug 2020 23:51:11
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'		13 Aug 2020 02:09:07
answered with 'confirmed' (Site from System).		
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	13 Aug 2020 02:08:54
User entered 'un UNK 2000'	(b) (4), (b) (6)	13 Aug 2020 02:08:54

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:41:32**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered '0'		13 Aug 2020 02:08:54

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:41:32**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Yes (Y)'		13 Aug 2020 02:08:54



**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:41:32**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.		13 Aug 2020 02:08:54

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:41:32**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'No (N)'		13 Aug 2020 02:08:54

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:41:32**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 02:08:54

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:41:32**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 02:08:54

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:41:32**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 02:08:54

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:41:32

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 20:51:33
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 20:51:33
	(b) (4)	
Data point term sent to Coder	System	05 Nov 2020 20:35:52
User entered 'Aspirin'	Danuel Hamlin (b) (4)	05 Nov 2020 20:35:11

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:41:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Yes (Y)'	Danuel Hamlin (b) (4) [REDACTED] [REDACTED]	05 Nov 2020 20:35:11

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:41:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Cardiac Prophylaxis'	Danuel Hamlin (b) (4) [REDACTED] [REDACTED]	05 Nov 2020 20:35:11



US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:41:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered '81'	Danuel Hamlin (b) (4) [REDACTED] [REDACTED]	05 Nov 2020 20:35:11

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:41:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'mg (mg)'	Danuel Hamlin (b) (4) [REDACTED] [REDACTED]	05 Nov 2020 20:35:11

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:41:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	Danuel Hamlin (b) (4)  	05 Nov 2020 20:35:11

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:41:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'once daily (QD)'	Danuel Hamlin (b) (4)  	05 Nov 2020 20:35:11

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:41:32

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	Danuel Hamlin (b) (4) [REDACTED] [REDACTED]	05 Nov 2020 20:35:11

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:41:32

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Oral (ORAL)'	Danuel Hamlin (b) (4)  	05 Nov 2020 20:35:11

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:41:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	Danuel Hamlin (b) (4)  	05 Nov 2020 20:35:11

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:41:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered '09 Sep 2020'	Danuel Hamlin (b) (4)  	05 Nov 2020 20:35:11



US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:41:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered '0'	Danuel Hamlin (b) (4)  	05 Nov 2020 20:35:11

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:41:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Yes (Y)'	Danuel Hamlin (b) (4) [REDACTED] [REDACTED]	05 Nov 2020 20:35:11

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:41:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	Danuel Hamlin (b) (4)  	05 Nov 2020 20:35:11

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:41:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'No (N)'	Danuel Hamlin (b) (4)  	05 Nov 2020 20:35:11

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:41:32**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 20:35:11

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:41:32**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 20:35:11

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:41:32**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Nov 2020 20:35:11

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:41:32

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 07:44:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 07:44:54
Data point term sent to Coder	System	02 Mar 2021 20:16:23
Coding entries removed.	(b) (4), (b) (6)	02 Mar 2021 20:15:49
User signature succeeded.	Gregg Lucksinger (b) (4) (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 21:15:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 21:15:23
Data point term sent to Coder	System	05 Nov 2020 20:37:56
User entered 'Atorvastatin'	Danuel Hamlin (b) (4)	05 Nov 2020 20:37:22



US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:41:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'No (N)'	Danuel Hamlin (b) (4)  	05 Nov 2020 20:37:22

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:41:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	02 Apr 2021 16:39:26
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:15:49
Signature has been broken.		02 Mar 2021 20:15:49
User entered 'FAMILIAL CARDIOMYOPATHY/ Congestive Heart Failure' reason for change: Data Entry Error		02 Mar 2021 20:15:49
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Familial Cardiomyopathy'	Danuel Hamlin (b) (4)	05 Nov 2020 20:37:22

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:41:32**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered '40'	Danuel Hamlin (b) (4)  	05 Nov 2020 20:37:22

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:41:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'mg (mg)'	Danuel Hamlin (b) (4)  	05 Nov 2020 20:37:22

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:41:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	Danuel Hamlin (b) (4)  	05 Nov 2020 20:37:22

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:41:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'once daily (QD)'	Danuel Hamlin (b) (4)  	05 Nov 2020 20:37:22

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:41:32

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	Danuel Hamlin (b) (4)  	05 Nov 2020 20:37:22

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:41:32**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Oral (ORAL)'	Danuel Hamlin (b) (4)  	05 Nov 2020 20:37:22



US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:41:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	Danuel Hamlin (b) (4) [REDACTED] [REDACTED]	05 Nov 2020 20:37:22

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:41:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered '08 Sep 2020'	Danuel Hamlin (b) (4) [REDACTED] [REDACTED]	05 Nov 2020 20:37:22

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:41:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered '0'	Danuel Hamlin (b) (4) [REDACTED] [REDACTED]	05 Nov 2020 20:37:22

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:41:32**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)  	05 Nov 2020 20:37:22

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:41:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	Danuel Hamlin (b) (4)  	05 Nov 2020 20:37:22

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:41:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'No (N)'	Danuel Hamlin (b) (4)  	05 Nov 2020 20:37:22

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:41:32**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 20:37:22

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:41:32**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 20:37:22



**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:41:32**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Nov 2020 20:37:22

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:41:32

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 12:48:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 12:48:59
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	02 Mar 2021 20:16:23 02 Mar 2021 20:16:01
User signature succeeded.	Gregg Lucksinger (b) (4) (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 21:34:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 21:34:29
Data point term sent to Coder User entered 'Carvedilol'	System Danuel Hamlin (b) (4)	05 Nov 2020 20:38:59 05 Nov 2020 20:38:09

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:41:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'No (N)'	Danuel Hamlin (b) (4)  	05 Nov 2020 20:38:09

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:41:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	02 Apr 2021 16:39:26
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:16:01
Signature has been broken.		02 Mar 2021 20:16:01
User entered 'FAMILIAL CARDIOMYOPATHY/ Congestive Heart Failure' reason for change: Data Entry Error		02 Mar 2021 20:16:01
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Familial Cardiomyopathy'	Danuel Hamlin (b) (4)	05 Nov 2020 20:38:09

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:41:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered '3.125'	Danuel Hamlin (b) (4)  	05 Nov 2020 20:38:09

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:41:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'mg (mg)'	Danuel Hamlin (b) (4)  	05 Nov 2020 20:38:09

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:41:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	Danuel Hamlin (b) (4)  	05 Nov 2020 20:38:09

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:41:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'twice daily (BID)'	Danuel Hamlin (b) (4) [REDACTED] [REDACTED]	05 Nov 2020 20:38:09



US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:41:32

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	Danuel Hamlin (b) (4) [REDACTED] [REDACTED]	05 Nov 2020 20:38:09

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:41:32**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Oral (ORAL)'	Danuel Hamlin (b) (4)  	05 Nov 2020 20:38:09

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:41:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	Danuel Hamlin (b) (4) [REDACTED] [REDACTED]	05 Nov 2020 20:38:09

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:41:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered '09 Sep 2020'	Danuel Hamlin (b) (4) [REDACTED] [REDACTED]	05 Nov 2020 20:38:09

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:41:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered '0'	Danuel Hamlin (b) (4) [REDACTED] [REDACTED]	05 Nov 2020 20:38:09

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:41:32**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)  	05 Nov 2020 20:38:09

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:41:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	Danuel Hamlin (b) (4)	05 Nov 2020 20:38:09

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:41:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'No (N)'	Danuel Hamlin (b) (4)  	05 Nov 2020 20:38:09



**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:41:32**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	05 Nov 2020 20:38:09

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:41:32**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 20:38:09

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:41:32**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Nov 2020 20:38:09

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:41:32

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 08:41:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 08:41:03
Data point term sent to Coder	System	02 Mar 2021 20:16:24
Coding entries removed.	(b) (4), (b) (6)	02 Mar 2021 20:16:20
User signature succeeded.	Gregg Lucksinger (b) (4) (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 22:36:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 22:36:31
Data point term sent to Coder	System	05 Nov 2020 20:38:59
User entered 'Furosemide'	Danuel Hamlin (b) (4)	05 Nov 2020 20:38:45

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:41:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'No (N)'	Danuel Hamlin (b) (4)  	05 Nov 2020 20:38:45

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:41:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	02 Apr 2021 16:39:26
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:16:20
Signature has been broken.		02 Mar 2021 20:16:20
User entered 'FAMILIAL CARDIOMYOPATHY/ Congestive Heart Failure' reason for change: Data Entry Error		02 Mar 2021 20:16:20
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Familial Cardiomyopathy'	Danuel Hamlin (b) (4)	05 Nov 2020 20:38:45

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:41:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered '20'	Danuel Hamlin (b) (4) [REDACTED] [REDACTED]	05 Nov 2020 20:38:45

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:41:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'mg (mg)'	Danuel Hamlin (b) (4)  	05 Nov 2020 20:38:45



US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:41:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	Danuel Hamlin (b) (4)  	05 Nov 2020 20:38:45

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:41:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'once daily (QD)'	Danuel Hamlin (b) (4)  	05 Nov 2020 20:38:45

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:41:32

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	Danuel Hamlin (b) (4) [REDACTED] [REDACTED]	05 Nov 2020 20:38:45

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:41:32**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Oral (ORAL)'	Danuel Hamlin (b) (4)  	05 Nov 2020 20:38:45

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:41:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	Danuel Hamlin (b) (4)  	05 Nov 2020 20:38:45

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:41:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered '10 Sep 2020'	Danuel Hamlin (b) (4)  	05 Nov 2020 20:38:45

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:41:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered '0'	Danuel Hamlin (b) (4) [REDACTED] [REDACTED]	05 Nov 2020 20:38:45

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:41:32**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)  	05 Nov 2020 20:38:45



US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:41:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	Danuel Hamlin (b) (4)  	05 Nov 2020 20:38:45

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:41:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'No (N)'	Danuel Hamlin (b) (4)  	05 Nov 2020 20:38:45

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:41:32**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 20:38:45

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:41:32**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 20:38:45

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:41:32**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Nov 2020 20:38:45

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:41:32

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Mar 2021 05:21:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Mar 2021 05:21:46
Data point term sent to Coder	System	02 Mar 2021 20:17:25
Coding entries removed.	(b) (4), (b) (6)	02 Mar 2021 20:16:39
User signature succeeded.	Gregg Lucksinger (b) (4) (b) (4)	19 Feb 2021 19:46:09
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 06:11:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 06:11:29
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
Data point term sent to Coder	System	05 Nov 2020 20:40:08
User entered 'Lisinopril'	Danuel Hamlin (b) (4)	05 Nov 2020 20:39:34

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:41:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'No (N)'	Danuel Hamlin (b) (4)  	05 Nov 2020 20:39:34

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:41:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	02 Apr 2021 16:39:26
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:16:39
Signature has been broken.		02 Mar 2021 20:16:39
User entered 'FAMILIAL CARDIOMYOPATHY/Congestive Heart Failure' reason for change: Data Entry Error		02 Mar 2021 20:16:39
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Familial Cardiomyopathy'	Danuel Hamlin (b) (4)	05 Nov 2020 20:39:34



US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:41:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered '2.5'	Danuel Hamlin (b) (4)	05 Nov 2020 20:39:34

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:41:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'mg (mg)'	Danuel Hamlin (b) (4)  	05 Nov 2020 20:39:34

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:41:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	Danuel Hamlin (b) (4)  	05 Nov 2020 20:39:34

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:41:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'once daily (QD)'	Danuel Hamlin (b) (4)  	05 Nov 2020 20:39:34

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:41:32

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	Danuel Hamlin (b) (4)  	05 Nov 2020 20:39:34

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:41:32**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Oral (ORAL)'	Danuel Hamlin (b) (4)  	05 Nov 2020 20:39:34

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:41:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	Danuel Hamlin (b) (4) [REDACTED] [REDACTED]	05 Nov 2020 20:39:34

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:41:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered '10 Sep 2020'	Danuel Hamlin (b) (4) [REDACTED] [REDACTED]	05 Nov 2020 20:39:34



US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:41:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered '0'	Danuel Hamlin (b) (4)	05 Nov 2020 20:39:34

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:41:32**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)  	05 Nov 2020 20:39:34

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:41:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	Danuel Hamlin (b) (4)  	05 Nov 2020 20:39:34

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:41:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'No (N)'	Danuel Hamlin (b) (4)  	05 Nov 2020 20:39:34

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:41:32**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 20:39:34

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:41:32**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 20:39:34

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:41:32**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Nov 2020 20:39:34

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:41:32

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: POTASSIUM-SPARING AGENTS, ATC: ALDOSTERONE ANTAGONISTS, PRODUCT: SPIRONOLACTONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Mar 2021 14:58:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Mar 2021 14:58:59
Data point term sent to Coder	System	02 Mar 2021 20:17:25
Coding entries removed.	(b) (4), (b) (6)	02 Mar 2021 20:16:53
User signature succeeded.	Gregg Lucksinger (b) (4) (b) (4)	19 Feb 2021 19:46:09
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: POTASSIUM-SPARING AGENTS, ATC: ALDOSTERONE ANTAGONISTS, PRODUCT: SPIRONOLACTONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 05:42:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 05:42:53
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
Data point term sent to Coder	System	05 Nov 2020 20:40:10
User entered 'Spironolactone'	Danuel Hamlin (b) (4)	05 Nov 2020 20:40:09



US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:41:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'No (N)'	Danuel Hamlin (b) (4) [REDACTED] [REDACTED]	05 Nov 2020 20:40:09

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:41:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	02 Apr 2021 16:39:26
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 20:16:53
Signature has been broken.		02 Mar 2021 20:16:53
User entered 'FAMILIAL CARDIOMYOPATHY/ Congestive Heart Failure' reason for change: Data Entry Error		02 Mar 2021 20:16:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Familial Cardiomyopathy'	Danuel Hamlin (b) (4)	05 Nov 2020 20:40:09

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:41:32

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 11:17:01
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'per source document ' (Site from DM).		01 Apr 2021 22:40:22
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).		12 Mar 2021 10:01:16
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered '6.25'	Danuel Hamlin (b) (4)	05 Nov 2020 20:40:09

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:41:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'mg (mg)'	Danuel Hamlin (b) (4)	05 Nov 2020 20:40:09

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:41:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	Danuel Hamlin (b) (4)  	05 Nov 2020 20:40:09

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:41:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'once daily (QD)'	Danuel Hamlin (b) (4)  	05 Nov 2020 20:40:09

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:41:32

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	Danuel Hamlin (b) (4)  	05 Nov 2020 20:40:09

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:41:32**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Oral (ORAL)'	Danuel Hamlin (b) (4)  	05 Nov 2020 20:40:09



US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:41:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	Danuel Hamlin (b) (4)  	05 Nov 2020 20:40:09

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:41:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered '10 Sep 2020'	Danuel Hamlin (b) (4)  	05 Nov 2020 20:40:09

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:41:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered '0'	Danuel Hamlin (b) (4) [REDACTED] [REDACTED]	05 Nov 2020 20:40:09

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:41:32**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)  	05 Nov 2020 20:40:09

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:41:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	Danuel Hamlin (b) (4)	05 Nov 2020 20:40:09

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:41:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'No (N)'	Danuel Hamlin (b) (4)  	05 Nov 2020 20:40:09

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:41:32**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 20:40:09

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:41:32**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 20:40:09



**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:41:32**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Nov 2020 20:40:09

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:41:32

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN GLARGINE, PRODUCTSYNONYM: LANTUS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 20:44:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 20:44:24
Data point term sent to Coder	System	05 Nov 2020 20:43:14
User entered 'Lantus'	Danuel Hamlin (b) (4)   	05 Nov 2020 20:42:20

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:41:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'No (N)'	Danuel Hamlin (b) (4)  	05 Nov 2020 20:42:20

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:41:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Type II Diabetes'	Danuel Hamlin (b) (4)  	05 Nov 2020 20:42:20

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:41:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered '22'	Danuel Hamlin (b) (4)  	05 Nov 2020 20:42:20

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:41:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Other (OTHER)'	Danuel Hamlin (b) (4)  	05 Nov 2020 20:42:20

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:41:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'units'	Danuel Hamlin (b) (4)  	05 Nov 2020 20:42:20

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:41:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'once daily (QD)'	Danuel Hamlin (b) (4)  	05 Nov 2020 20:42:20



US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:41:32

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	Danuel Hamlin (b) (4)  	05 Nov 2020 20:42:20

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:41:32

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Subcutaneous (SUBCUTANEOUS)'	Danuel Hamlin (b) (4) [REDACTED] [REDACTED]	05 Nov 2020 20:42:20

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:41:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	Danuel Hamlin (b) (4)  	05 Nov 2020 20:42:20

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:41:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'un UNK 2019'	Danuel Hamlin (b) (4) [REDACTED] [REDACTED]	05 Nov 2020 20:42:20

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:41:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered '0'	Danuel Hamlin (b) (4)  	05 Nov 2020 20:42:20

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:41:32**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)  	05 Nov 2020 20:42:20

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:41:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	Danuel Hamlin (b) (4)  	05 Nov 2020 20:42:20

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:41:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'No (N)'	Danuel Hamlin (b) (4)  	05 Nov 2020 20:42:20



**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:41:32**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 20:42:20

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:41:32**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 20:42:20

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:41:32**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Nov 2020 20:42:20

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:41:32

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Luck singer (b) (4)	19 Feb 2021 19:46:09
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN LISPRO - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	06 Nov 2020 06:14:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 06:14:30
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
Data point term sent to Coder	System	05 Nov 2020 20:44:18
User entered 'Insulin Lispro'	Daniel Hamlin (b) (4)	05 Nov 2020 20:44:03

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:41:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'No (N)'	Danuel Hamlin (b) (4)  	05 Nov 2020 20:44:03

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:41:32**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Type II Diabetes'	Danuel Hamlin (b) (4)  	05 Nov 2020 20:44:03

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:41:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered '2'	Danuel Hamlin (b) (4)  	05 Nov 2020 20:44:03

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:41:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Other (OTHER)'	Danuel Hamlin (b) (4)	05 Nov 2020 20:44:03



US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:41:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Units'	Danuel Hamlin (b) (4)  	05 Nov 2020 20:44:03

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:41:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'as needed (PRN)'	Danuel Hamlin (b) (4)  	05 Nov 2020 20:44:03

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:41:32

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	Danuel Hamlin (b) (4)  	05 Nov 2020 20:44:03

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:41:32

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Subcutaneous (SUBCUTANEOUS)'	Danuel Hamlin (b) (4) [REDACTED] [REDACTED]	05 Nov 2020 20:44:03

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:41:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	Danuel Hamlin (b) (4)  	05 Nov 2020 20:44:03

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:41:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'un UNK 2019'	Danuel Hamlin (b) (4)  	05 Nov 2020 20:44:03

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:41:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered '0'	Danuel Hamlin (b) (4)  	05 Nov 2020 20:44:03

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:41:32**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	05 Nov 2020 20:44:03



US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:41:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	Danuel Hamlin (b) (4)  	05 Nov 2020 20:44:03

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:41:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 20:44:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Nov 2020 20:44:08
User entered 'No (N)' reason for change: Data Entry Error	Danuel Hamlin (b) (4)	05 Nov 2020 20:44:08
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 20:44:03
User entered empty.	Danuel Hamlin (b) (4)	05 Nov 2020 20:44:03

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:41:32**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 20:44:03

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:41:32**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 20:44:03

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:41:32**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 20:44:03

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:41:32

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 06:27:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 06:27:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:38
Data point term sent to Coder	System	05 Nov 2020 20:48:44
User entered 'Albuterol'	Danuel Hamlin (b) (4)	05 Nov 2020 20:47:40

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:41:32**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'No (N)'	Danuel Hamlin (b) (4)  	05 Nov 2020 20:47:40

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:41:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Exertional Bronchospasm'	Danuel Hamlin (b) (4)  	05 Nov 2020 20:47:40



US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:41:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered '180'	Danuel Hamlin (b) (4)  	05 Nov 2020 20:47:40

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:41:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'ug (ug)'	Danuel Hamlin (b) (4)	05 Nov 2020 20:47:40

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:41:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	Danuel Hamlin (b) (4)  	05 Nov 2020 20:47:40

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:41:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'as needed (PRN)'	Danuel Hamlin (b) (4)  	05 Nov 2020 20:47:40

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:41:32

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	Danuel Hamlin (b) (4)	05 Nov 2020 20:47:40

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:41:32**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Danuel Hamlin (b) (4) [REDACTED] [REDACTED]	05 Nov 2020 20:47:40

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:41:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	Danuel Hamlin (b) (4)  	05 Nov 2020 20:47:40

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:41:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'un UNK 2018'	Danuel Hamlin (b) (4)  	05 Nov 2020 20:47:40



US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:41:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered '0'	Danuel Hamlin (b) (4)	05 Nov 2020 20:47:40

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:41:32**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)  	05 Nov 2020 20:47:40

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:41:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered empty.	Danuel Hamlin (b) (4)  	05 Nov 2020 20:47:40

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:41:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:38
User entered 'No (N)'	Danuel Hamlin (b) (4)  	05 Nov 2020 20:47:40

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:41:32**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 20:47:40

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:41:32**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 20:47:40

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:41:32**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 20:47:40

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:41:32

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN SODIUM, PRODUCTSYNONYM: LOVENOX [ENOXAPARIN SODIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Apr 2021 19:52:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Apr 2021 19:52:37
Data point term sent to Coder	System	12 Apr 2021 18:42:57
User entered 'Lovenox'	(b) (4), (b) (6)	12 Apr 2021 18:42:42



US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:41:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:42:42

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:41:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered 'Cardiac prophylaxis'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:42:42

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:41:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered '30'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:42:42

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:41:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:42:42

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:41:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:42:42

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:41:32**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:42:42

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:41:32

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:42:42

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:41:32

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:42:42



US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:41:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	12 Apr 2021 18:42:42

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:41:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered '15 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:42:42

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:41:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:42:42

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:41:32**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:42:42

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:41:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
	(b) (4)	
User entered '07 Apr 2021'	(b) (4), (b) (6)	12 Apr 2021 18:42:42

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:41:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:42:42

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:41:32**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	12 Apr 2021 18:42:42

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:41:32**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Apr 2021 18:42:42



**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:41:32**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Apr 2021 18:42:42

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:41:32

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:21:38
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: ANESTHETICS, GENERAL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 14:40:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 14:40:56
User signature succeeded.	Gregg Lucksinger (b) (4) (b) (4)	13 Apr 2021 00:44:54
Data point term sent to Coder	System	12 Apr 2021 18:50:37
User entered 'General Anesthesia'	(b) (4), (b) (6)  (b) (4)	12 Apr 2021 18:50:27

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:41:32

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:21:38
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered 'No (N)'	(b) (4), (b) (6)	12 Apr 2021 18:50:27

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:41:32

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:21:38
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered 'L below the knee amputation'	(b) (4), (b) (6)	12 Apr 2021 18:50:27

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:41:32**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:21:38
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered 'unk'	(b) (4), (b) (6)	12 Apr 2021 18:50:27

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:41:32

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:21:38
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered 'Other (OTHER)'	(b) (4), (b) (6)	12 Apr 2021 18:50:27

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:41:32

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:21:38
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered 'unknown'	(b) (4), (b) (6)	12 Apr 2021 18:50:27

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:41:32

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:21:38
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered 'once (ONCE)'	(b) (4), (b) (6)	12 Apr 2021 18:50:27



US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:41:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:21:38
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered empty.	(b) (4), (b) (6)	12 Apr 2021 18:50:27

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:41:32

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:21:38
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:50:27

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:41:32

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:21:38
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered empty.	(b) (4), (b) (6)	12 Apr 2021 18:50:27

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:41:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:21:38
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered '15 Mar 2021'	(b) (4), (b) (6)	12 Apr 2021 18:50:27

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:41:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:21:38
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered '0'	(b) (4), (b) (6)	12 Apr 2021 18:50:27

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:41:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:21:38
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered 'No (N)'	(b) (4), (b) (6)	12 Apr 2021 18:50:27

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:41:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:21:38
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered '15 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:50:27

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:41:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:21:38
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered 'No (N)'	(b) (4), (b) (6)	12 Apr 2021 18:50:27



**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:41:32**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:21:38
User entered empty.	System	12 Apr 2021 18:50:27

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:41:32**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:21:38
User entered empty.	System	12 Apr 2021 18:50:27

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:41:32**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:21:38
User entered empty.	System	12 Apr 2021 18:50:27

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:41:32

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: ANESTHETICS, GENERAL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 14:40:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 14:40:55
User signature succeeded.	Gregg Lucksinger (b) (4) (b) (4)	13 Apr 2021 00:44:54
Data point term sent to Coder System		12 Apr 2021 18:51:38
User entered 'general anesthesia'	(b) (4), (b) (6) [REDACTED] [REDACTED]	12 Apr 2021 18:51:14

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:41:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:51:14

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:41:32**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered 'R below the knee amputation'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:51:14

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:41:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered 'unk'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:51:14

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:41:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:51:14



US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:41:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered 'unknown'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:51:14

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:41:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:51:14

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:41:32

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:51:14

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:41:32**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:51:14

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:41:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 18:51:14

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:41:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered '29 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:51:14

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:41:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:51:14

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:41:32**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:51:14



US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:41:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered '29 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:51:14

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:41:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:51:14

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:41:32**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 18:51:14

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:41:32**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 18:51:14

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:41:32**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 18:51:14

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:41:32

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:21:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: NORCO - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	12 Apr 2021 20:03:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 20:03:30
Data point term sent to Coder	System	12 Apr 2021 18:52:46
User entered 'Norco'	(b) (4), (b) (6)	12 Apr 2021 18:52:06

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:41:32

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:21:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered 'No (N)'	(b) (4), (b) (6)	12 Apr 2021 18:52:06

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:41:32

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:21:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered 'Bilateral chronic foot pain'	(b) (4), (b) (6)	12 Apr 2021 18:52:06



US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:41:32

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:21:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered '300/5'	(b) (4), (b) (6)	12 Apr 2021 18:52:06

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:41:32

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:21:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered 'mg (mg)'	(b) (4), (b) (6)	12 Apr 2021 18:52:06

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:41:32

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:21:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered empty.	(b) (4), (b) (6)	12 Apr 2021 18:52:06

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:41:32

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:21:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered 'once daily (QD)'	(b) (4), (b) (6)	12 Apr 2021 18:52:06

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:41:32

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:21:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered empty.	(b) (4), (b) (6)	12 Apr 2021 18:52:06

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:41:32**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:21:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	12 Apr 2021 18:52:06

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:41:32

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:21:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered empty.	(b) (4), (b) (6)	12 Apr 2021 18:52:06

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:41:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:21:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered '01 Mar 2021'	(b) (4), (b) (6)	12 Apr 2021 18:52:06



US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:41:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:21:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered '0'	(b) (4), (b) (6)	12 Apr 2021 18:52:06

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:41:32**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:21:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered 'No (N)'	(b) (4), (b) (6)	12 Apr 2021 18:52:06

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:41:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:21:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered '14 Mar 2021'	(b) (4), (b) (6)	12 Apr 2021 18:52:06

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:41:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:21:42
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered 'No (N)'	(b) (4), (b) (6)	12 Apr 2021 18:52:06

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:41:32**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:21:42
User entered '1'	System	12 Apr 2021 18:52:06

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:41:32**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:21:42
User entered '1'	System	12 Apr 2021 18:52:06

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:41:32**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:21:42
User entered '804 (804)'	System	12 Apr 2021 18:52:06

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:41:32

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: NORCO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Apr 2021 20:04:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Apr 2021 20:04:29
Data point term sent to Coder	System	12 Apr 2021 18:53:47
User entered 'Norco'	(b) (4), (b) (6)	12 Apr 2021 18:52:47



US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:41:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:52:47

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:41:32**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered 'post-surgical pain'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:52:47

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:41:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered '300/5'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:52:47

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:41:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:52:47

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:41:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:52:47

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:41:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:52:47

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:41:32

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:52:47

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:41:32**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:52:47



US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:41:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 18:52:47

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:41:32**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered '15 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:52:47

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:41:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:52:47

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:41:32**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:52:47

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:41:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	12 Apr 2021 18:52:47

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:41:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:52:47

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:41:32**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Apr 2021 18:52:47

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:41:32**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Apr 2021 18:52:47



**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:41:32**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Apr 2021 18:52:47

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:41:32

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:21:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: CARBAMIC ACID ESTERS, PRODUCT: METHOCARBAMOL, PRODUCTSYNONYM: ROBAXIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	12 Apr 2021 20:04:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 20:04:28
Data point term sent to Coder	System	12 Apr 2021 18:53:47
User entered 'Robaxin'	(b) (4), (b) (6)	12 Apr 2021 18:53:36

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:41:32

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:21:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered 'No (N)'	(b) (4), (b) (6)	12 Apr 2021 18:53:36

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:41:32

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:21:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered 'bilateral chronic foot pain'	(b) (4), (b) (6)	12 Apr 2021 18:53:36

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:41:32**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:21:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered '1000'	(b) (4), (b) (6)	12 Apr 2021 18:53:36

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:41:32

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:21:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered 'mg (mg)'	(b) (4), (b) (6)	12 Apr 2021 18:53:36

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:41:32

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:21:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered empty.	(b) (4), (b) (6)	12 Apr 2021 18:53:36

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:41:32

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:21:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered 'once daily (QD)'	(b) (4), (b) (6)	12 Apr 2021 18:53:36



US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:41:32

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:21:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered empty.	(b) (4), (b) (6)	12 Apr 2021 18:53:36

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:41:32

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:21:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	12 Apr 2021 18:53:36

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:41:32

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:21:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered empty.	(b) (4), (b) (6)	12 Apr 2021 18:53:36

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:41:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:21:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered '01 Mar 2021'	(b) (4), (b) (6)	12 Apr 2021 18:53:36

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:41:32**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:21:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered '0'	(b) (4), (b) (6)	12 Apr 2021 18:53:36

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:41:32**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:21:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered 'No (N)'	(b) (4), (b) (6)	12 Apr 2021 18:53:36

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:41:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:21:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered '14 Mar 2021'	(b) (4), (b) (6)	12 Apr 2021 18:53:36

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:41:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:21:47
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered 'No (N)'	(b) (4), (b) (6)	12 Apr 2021 18:53:36



**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:41:32**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:21:47
User entered '1'	System	12 Apr 2021 18:53:36

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:41:32**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:21:47
User entered '1'	System	12 Apr 2021 18:53:36

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:41:32**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:21:47
User entered '804 (804)'	System	12 Apr 2021 18:53:36

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:41:32

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: CARBAMIC ACID ESTERS, PRODUCT: METHOCARBAMOL, PRODUCTSYNONYM: ROBAXIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Apr 2021 20:04:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Apr 2021 20:04:50
Data point term sent to Coder	System	12 Apr 2021 18:54:48
User entered 'Robaxin'	(b) (4), (b) (6)	12 Apr 2021 18:54:10

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:41:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:54:10

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:41:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered 'post-surgical pain'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:54:10

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:41:32**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered '1000'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:54:10

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:41:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:54:10



US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:41:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:54:10

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:41:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:54:10

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:41:32

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:54:10

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:41:32

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:54:10

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:41:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 18:54:10

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:41:32**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered '15 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:54:10

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:41:32**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:54:10

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:41:32**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:54:10



US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:41:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	12 Apr 2021 18:54:10

US3462116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:41:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:54:10

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:41:32**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Apr 2021 18:54:10

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:41:32**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Apr 2021 18:54:10

**US3462116**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:41:32**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Apr 2021 18:54:10

US3462116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:41:32

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:27:56
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 15:38:52

US3462116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:41:32

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
User entered '05 Sep 2020'	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 15:39:22

US3462116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:41:32

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
User entered 'Echocardiogram'	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 15:39:22



US3462116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:41:32

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
User entered 'Adverse Event (AE)'	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 15:39:22

US3462116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:41:32

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 15:39:22

US3462116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:41:32

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:04
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
User entered '05 Sep 2020'	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 15:40:09

US3462116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:41:32

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:04
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
User entered 'CAT Scan'	Danuel Hamlin (b) (4)	04 Nov 2020 15:40:09

US3462116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:41:32

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:04
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
User entered 'Adverse Event (AE)'	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 15:40:09

US3462116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:41:32

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:04
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 15:40:09

US3462116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:41:32

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
User entered '04 Sep 2020'	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 15:40:40

US3462116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:41:32

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
User entered 'Chest X-ray'	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 15:40:40



US3462116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:41:32

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
User entered 'Adverse Event (AE)'	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 15:40:40

US3462116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:41:32

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:05
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 15:40:40

US3462116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:41:32

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:07
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
User entered '08 Sep 2020'	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 15:41:10

US3462116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:41:32

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:07
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
User entered 'Angiogram'	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 15:41:10

US3462116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:41:32

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:07
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
User entered 'Adverse Event (AE)'	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 15:41:10

US3462116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:41:32

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:07
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	04 Nov 2020 15:41:10

US3462116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:41:32

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:09
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered '15 Mar 2021'	(b) (4), (b) (6)	12 Apr 2021 18:40:29

US3462116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:41:32

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:09
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered 'L Below the knee amputation'	(b) (4), (b) (6)	12 Apr 2021 18:40:29



US3462116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:41:32

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:09
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered 'Medical History (MH)'	(b) (4), (b) (6)	12 Apr 2021 18:40:29

US3462116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:41:32

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:09
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered empty.	(b) (4), (b) (6)	12 Apr 2021 18:40:29

US3462116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:41:32

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
	(b) (4)	
User entered '29 Mar 2021'	(b) (4), (b) (6)	12 Apr 2021 18:40:53

US3462116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:41:32

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered 'R below the knee amputation'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:40:53

US3462116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:41:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
User entered 'Medical History (MH)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:40:53

US3462116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:41:32

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Apr 2021 00:44:54
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	12 Apr 2021 18:40:53

**US3462116**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:41:32**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:47:54
Reviewed for Safety.		12 Sep 2020 15:31:44
User entered 'USA-US093-2020-MRNA-1273-P301000003'	System	12 Sep 2020 15:31:11

**US3462116**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:41:32**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:47:54
Reviewed for Safety.		12 Sep 2020 15:31:44
User entered 'Yes (Y)'	System	12 Sep 2020 15:31:11



**US3462116**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:41:32**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:47:54
Reviewed for Safety.		12 Sep 2020 15:31:44
User entered 'No (N)'	System	12 Sep 2020 15:31:11

**US3462116**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:41:32**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:47:54
Reviewed for Safety.		12 Sep 2020 15:31:44
User entered 'No (N)'	System	12 Sep 2020 15:31:11

**US3462116**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:41:32**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:47:54
Reviewed for Safety.		12 Sep 2020 15:31:44
User entered 'Yes (Y)'	System	12 Sep 2020 15:31:11

**US3462116**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:41:32**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:47:54
Reviewed for Safety.		12 Sep 2020 15:31:44
User entered 'No (N)'	System	12 Sep 2020 15:31:11

**US3462116**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:41:32**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:47:54
Reviewed for Safety.		12 Sep 2020 15:31:44
User entered 'No (N)'	System	12 Sep 2020 15:31:11

**US3462116**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:41:32**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:47:54
Reviewed for Safety.		12 Sep 2020 15:31:44
User entered 'No (N)'	System	12 Sep 2020 15:31:11

**US3462116**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:41:32**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
Reviewed for Safety.	(b) (4) (D) (4), (b) (6)	30 Nov 2020 18:56:49
DataPoint Verified.		05 Nov 2020 22:47:54
Amendment Manager: User entered 'Edward'	System	14 Sep 2020 21:48:58

**US3462116**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:41:32**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 18:56:49
DataPoint Verified.		05 Nov 2020 22:47:54
Amendment Manager: User entered 'Kerwin'	System	14 Sep 2020 21:48:58



**US3462116**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:41:32**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
Reviewed for Safety.	(b) (4) (D) (4), (b) (6)	30 Nov 2020 18:56:49
DataPoint Verified.		05 Nov 2020 22:47:54
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 06:32:40
User entered 'US' (non-conformant).	System	12 Sep 2020 15:31:50

US3462116

Folder: SAE USA-US093-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:32

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Signature has been broken.	System	25 Feb 2021 17:19:51
User entered '5'	System	25 Feb 2021 17:19:51
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
	(b) (4)	
User entered '4'	System	16 Feb 2021 17:43:11
User entered '3'	System	30 Nov 2020 18:57:23
User entered '2'	System	06 Nov 2020 18:49:00
User entered '1'	System	12 Sep 2020 15:31:50

**US3462116**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:41:32**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:47:54
Reviewed for Safety.		12 Sep 2020 15:31:44
User entered 'USA-US093-2020-MRNA-1273-P301000003'	System	12 Sep 2020 15:31:11

**US3462116**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:41:32**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:47:54
Reviewed for Safety.		12 Sep 2020 15:31:44
User entered 'Yes (Y)'	System	12 Sep 2020 15:31:11

**US3462116**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:41:32**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	05 Nov 2020 22:47:54
Reviewed for Safety.		12 Sep 2020 15:31:44
User entered 'No (N)'	System	12 Sep 2020 15:31:11

**US3462116**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:41:32**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:47:54
Reviewed for Safety.		12 Sep 2020 15:31:44
User entered 'No (N)'	System	12 Sep 2020 15:31:11

**US3462116**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:41:32**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:47:54
Reviewed for Safety.		12 Sep 2020 15:31:44
User entered 'Yes (Y)'	System	12 Sep 2020 15:31:11

**US3462116**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:41:32**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:47:54
Reviewed for Safety.		12 Sep 2020 15:31:44
User entered 'No (N)'	System	12 Sep 2020 15:31:11



**US3462116**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:41:32**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:47:54
Reviewed for Safety.		12 Sep 2020 15:31:44
User entered 'No (N)'	System	12 Sep 2020 15:31:11

**US3462116**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:41:32**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:47:54
Reviewed for Safety.		12 Sep 2020 15:31:44
User entered 'No (N)'	System	12 Sep 2020 15:31:11

**US3462116**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:41:32**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
Reviewed for Safety.	(b) (4) (d) (4), (b) (6)	30 Nov 2020 18:56:49
DataPoint Verified.		05 Nov 2020 22:47:54
Amendment Manager: User entered 'Edward'	System	14 Sep 2020 21:48:58

**US3462116**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:41:32**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 18:56:49
DataPoint Verified.		05 Nov 2020 22:47:54
Amendment Manager: User entered 'Kerwin'	System	14 Sep 2020 21:48:58

**US3462116**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:41:32**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 18:56:49
DataPoint Verified.		05 Nov 2020 22:47:54
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 06:32:40
User entered 'US' (non-conformant).	System	12 Sep 2020 15:31:50

US3462116

Folder: SAE USA-US093-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:32

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Signature has been broken.	System	25 Feb 2021 17:19:51
User entered '5'	System	25 Feb 2021 17:19:51
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
	(b) (4)	
User entered '4'	System	16 Feb 2021 17:43:11
User entered '3'	System	30 Nov 2020 18:57:23
User entered '2'	System	06 Nov 2020 18:49:00
User entered '1'	System	12 Sep 2020 15:31:50

**US3462116**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 17:41:32**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:47:54
User entered '12/Sep/2020 11:31'	System	12 Sep 2020 15:31:50

US3462116

Folder: SAE USA-US093-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:41:32

**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.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 18:56:49
DataPoint Verified.		05 Nov 2020 22:47:54
User entered 'I'		12 Sep 2020 15:31:50



**US3462116**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:41:32**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	05 Nov 2020 22:47:54
Reviewed for Safety.		12 Sep 2020 15:31:44
User entered 'USA-US093-2020-MRNA-1273-P301000003'	System	12 Sep 2020 15:31:11

**US3462116**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:41:32**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:47:54
Reviewed for Safety.		12 Sep 2020 15:31:44
User entered 'Yes (Y)'	System	12 Sep 2020 15:31:11

**US3462116**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:41:32**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	05 Nov 2020 22:47:54
Reviewed for Safety.		12 Sep 2020 15:31:44
User entered 'No (N)'	System	12 Sep 2020 15:31:11

**US3462116**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:41:32**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:47:54
Reviewed for Safety.		12 Sep 2020 15:31:44
User entered 'No (N)'	System	12 Sep 2020 15:31:11

**US3462116**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:41:32**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:47:54
Reviewed for Safety.		12 Sep 2020 15:31:44
User entered 'Yes (Y)'	System	12 Sep 2020 15:31:11

**US3462116**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:41:32**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:47:54
Reviewed for Safety.		12 Sep 2020 15:31:44
User entered 'No (N)'	System	12 Sep 2020 15:31:11

**US3462116**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:41:32**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:47:54
Reviewed for Safety.		12 Sep 2020 15:31:44
User entered 'No (N)'	System	12 Sep 2020 15:31:11

**US3462116**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:41:32**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:47:54
Reviewed for Safety.		12 Sep 2020 15:31:44
User entered 'No (N)'	System	12 Sep 2020 15:31:11



**US3462116**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:41:32**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
Reviewed for Safety.	(b) (4) (d) (4), (b) (6)	30 Nov 2020 18:56:49
DataPoint Verified.		05 Nov 2020 22:47:54
Amendment Manager: User entered 'Edward'	System	14 Sep 2020 21:48:58

**US3462116**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:41:32**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
Reviewed for Safety.	(b) (4) (D) (4), (b) (6)	30 Nov 2020 18:56:49
DataPoint Verified.		05 Nov 2020 22:47:54
Amendment Manager: User entered 'Kerwin'	System	14 Sep 2020 21:48:58

**US3462116**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:41:32**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
Reviewed for Safety.	(b) (4) (D) (4), (b) (6)	30 Nov 2020 18:56:49
DataPoint Verified.		05 Nov 2020 22:47:54
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 06:32:40
User entered 'US' (non-conformant).	System	12 Sep 2020 15:31:50

US3462116

Folder: SAE USA-US093-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:32

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Signature has been broken.	System	25 Feb 2021 17:19:51
User entered '5'	System	25 Feb 2021 17:19:51
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
	(b) (4)	
User entered '4'	System	16 Feb 2021 17:43:11
User entered '3'	System	30 Nov 2020 18:57:23
User entered '2'	System	06 Nov 2020 18:49:00
User entered '1'	System	12 Sep 2020 15:31:50

**US3462116**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 17:41:32**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
User entered '06/Nov/2020 13:48'	(b) (4) System	06 Nov 2020 18:49:00

US3462116

Folder: SAE USA-US093-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:41:32

**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.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 18:56:49
User entered 'I'		06 Nov 2020 18:49:00

**US3462116**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:41:32**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:47:54
Reviewed for Safety.		12 Sep 2020 15:31:44
User entered 'USA-US093-2020-MRNA-1273-P301000003'	System	12 Sep 2020 15:31:11

**US3462116**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:41:32**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	05 Nov 2020 22:47:54
Reviewed for Safety.		12 Sep 2020 15:31:44
User entered 'Yes (Y)'	System	12 Sep 2020 15:31:11



**US3462116**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:41:32**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	05 Nov 2020 22:47:54
Reviewed for Safety.		12 Sep 2020 15:31:44
User entered 'No (N)'	System	12 Sep 2020 15:31:11

**US3462116**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:41:32**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:47:54
Reviewed for Safety.		12 Sep 2020 15:31:44
User entered 'No (N)'	System	12 Sep 2020 15:31:11

**US3462116**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:41:32**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:47:54
Reviewed for Safety.		12 Sep 2020 15:31:44
User entered 'Yes (Y)'	System	12 Sep 2020 15:31:11

**US3462116**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:41:32**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:47:54
Reviewed for Safety.		12 Sep 2020 15:31:44
User entered 'No (N)'	System	12 Sep 2020 15:31:11

**US3462116**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:41:32**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:47:54
Reviewed for Safety.		12 Sep 2020 15:31:44
User entered 'No (N)'	System	12 Sep 2020 15:31:11

**US3462116**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:41:32**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:47:54
Reviewed for Safety.		12 Sep 2020 15:31:44
User entered 'No (N)'	System	12 Sep 2020 15:31:11

**US3462116**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:41:32**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
Reviewed for Safety.	(b) (4) (D) (4), (b) (6)	30 Nov 2020 18:56:49
DataPoint Verified.		05 Nov 2020 22:47:54
Amendment Manager: User entered 'Edward'	System	14 Sep 2020 21:48:58

**US3462116**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:41:32**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	30 Nov 2020 18:56:49
DataPoint Verified.		05 Nov 2020 22:47:54
Amendment Manager: User entered 'Kerwin'	System	14 Sep 2020 21:48:58



**US3462116**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:41:32**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 18:56:49
DataPoint Verified.		05 Nov 2020 22:47:54
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 06:32:40
User entered 'US' (non-conformant).	System	12 Sep 2020 15:31:50

US3462116

Folder: SAE USA-US093-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:32

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Signature has been broken.	System	25 Feb 2021 17:19:51
User entered '5'	System	25 Feb 2021 17:19:51
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
	(b) (4)	
User entered '4'	System	16 Feb 2021 17:43:11
User entered '3'	System	30 Nov 2020 18:57:23
User entered '2'	System	06 Nov 2020 18:49:00
User entered '1'	System	12 Sep 2020 15:31:50

**US3462116**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 17:41:32**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
User entered '30/Nov/2020 18:57'	(b) (4) System	30 Nov 2020 18:57:23

US3462116

Folder: SAE USA-US093-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:41:32

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 17:20:41
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
User entered 'I'	(b) (4), (b) (6)	30 Nov 2020 18:57:23

**US3462116**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:41:32**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:47:54
Reviewed for Safety.		12 Sep 2020 15:31:44
User entered 'USA-US093-2020-MRNA-1273-P301000003'	System	12 Sep 2020 15:31:11

**US3462116**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:41:32**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:47:54
Reviewed for Safety.		12 Sep 2020 15:31:44
User entered 'Yes (Y)'	System	12 Sep 2020 15:31:11

**US3462116**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:41:32**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:47:54
Reviewed for Safety.		12 Sep 2020 15:31:44
User entered 'No (N)'	System	12 Sep 2020 15:31:11

**US3462116**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:41:32**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:47:54
Reviewed for Safety.		12 Sep 2020 15:31:44
User entered 'No (N)'	System	12 Sep 2020 15:31:11



**US3462116**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:41:32**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:47:54
Reviewed for Safety.		12 Sep 2020 15:31:44
User entered 'Yes (Y)'	System	12 Sep 2020 15:31:11

**US3462116**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:41:32**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:47:54
Reviewed for Safety.		12 Sep 2020 15:31:44
User entered 'No (N)'	System	12 Sep 2020 15:31:11

**US3462116**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:41:32**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:47:54
Reviewed for Safety.		12 Sep 2020 15:31:44
User entered 'No (N)'	System	12 Sep 2020 15:31:11

**US3462116**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:41:32**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:47:54
Reviewed for Safety.		12 Sep 2020 15:31:44
User entered 'No (N)'	System	12 Sep 2020 15:31:11

**US3462116**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:41:32**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
Reviewed for Safety.	(b) (4) (D) (4), (b) (6)	30 Nov 2020 18:56:49
DataPoint Verified.		05 Nov 2020 22:47:54
Amendment Manager: User entered 'Edward'	System	14 Sep 2020 21:48:58

**US3462116**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:41:32**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
Reviewed for Safety.	(b) (4) (D) (4), (b) (6)	30 Nov 2020 18:56:49
DataPoint Verified.		05 Nov 2020 22:47:54
Amendment Manager: User entered 'Kerwin'	System	14 Sep 2020 21:48:58

**US3462116**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:41:32**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
Reviewed for Safety.	(b) (4) (D) (4), (b) (6)	30 Nov 2020 18:56:49
DataPoint Verified.		05 Nov 2020 22:47:54
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 06:32:40
User entered 'US' (non-conformant).	System	12 Sep 2020 15:31:50

US3462116

Folder: SAE USA-US093-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:32

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Signature has been broken.	System	25 Feb 2021 17:19:51
User entered '5'	System	25 Feb 2021 17:19:51
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
	(b) (4)	
User entered '4'	System	16 Feb 2021 17:43:11
User entered '3'	System	30 Nov 2020 18:57:23
User entered '2'	System	06 Nov 2020 18:49:00
User entered '1'	System	12 Sep 2020 15:31:50



**US3462116**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (4)**

**Generated On: 09 Jun 2021 17:41:32**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
User entered '16/Feb/2021 12:43'	(b) (4) System	16 Feb 2021 17:43:11

US3462116

Folder: SAE USA-US093-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:41:32

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 17:20:41
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
User entered 'I'	(b) (4), (b) (6)	16 Feb 2021 17:43:11

**US3462116**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:41:32**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:47:54
Reviewed for Safety.		12 Sep 2020 15:31:44
User entered 'USA-US093-2020-MRNA-1273-P301000003'	System	12 Sep 2020 15:31:11

**US3462116**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:41:32**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:47:54
Reviewed for Safety.		12 Sep 2020 15:31:44
User entered 'Yes (Y)'	System	12 Sep 2020 15:31:11

**US3462116**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:41:32**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:47:54
Reviewed for Safety.		12 Sep 2020 15:31:44
User entered 'No (N)'	System	12 Sep 2020 15:31:11

**US3462116**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:41:32**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:47:54
Reviewed for Safety.		12 Sep 2020 15:31:44
User entered 'No (N)'	System	12 Sep 2020 15:31:11

**US3462116**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:41:32**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:47:54
Reviewed for Safety.		12 Sep 2020 15:31:44
User entered 'Yes (Y)'	System	12 Sep 2020 15:31:11

**US3462116**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:41:32**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:47:54
Reviewed for Safety.		12 Sep 2020 15:31:44
User entered 'No (N)'	System	12 Sep 2020 15:31:11



**US3462116**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:41:32**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	05 Nov 2020 22:47:54
Reviewed for Safety.		12 Sep 2020 15:31:44
User entered 'No (N)'	System	12 Sep 2020 15:31:11

**US3462116**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:41:32**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:47:54
Reviewed for Safety.		12 Sep 2020 15:31:44
User entered 'No (N)'	System	12 Sep 2020 15:31:11

**US3462116**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:41:32**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 18:56:49
DataPoint Verified.		05 Nov 2020 22:47:54
Amendment Manager: User entered 'Edward'	System	14 Sep 2020 21:48:58

**US3462116**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:41:32**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 18:56:49
DataPoint Verified.		05 Nov 2020 22:47:54
Amendment Manager: User entered 'Kerwin'	System	14 Sep 2020 21:48:58

US3462116

Folder: SAE USA-US093-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:32

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 18:56:49
DataPoint Verified.		05 Nov 2020 22:47:54
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 06:32:40
User entered 'US' (non-conformant).	System	12 Sep 2020 15:31:50

US3462116

Folder: SAE USA-US093-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:32

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Signature has been broken.	System	25 Feb 2021 17:19:51
User entered '5'	System	25 Feb 2021 17:19:51
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:46:09
	(b) (4)	
User entered '4'	System	16 Feb 2021 17:43:11
User entered '3'	System	30 Nov 2020 18:57:23
User entered '2'	System	06 Nov 2020 18:49:00
User entered '1'	System	12 Sep 2020 15:31:50

**US3462116**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (5)**

**Generated On: 09 Jun 2021 17:41:32**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
User entered '25/Feb/2021 12:19'	(b) (4) System	25 Feb 2021 17:19:51

US3462116

Folder: SAE USA-US093-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:41:32

**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.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:07:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:20:41
User entered 'I'		25 Feb 2021 17:19:51