

US3032115 (Prod: Meridian Clinical Research (Norfolk-Nebraska))

Generated By: KC Joubran

Generated On: 09 Jun 2021 14:48:59

All time stamps listed in this document are displayed in GMT

US3032115

Form: Participant Creation

Data signed: (b) (4) 28 Sep 2020 16:59:27

Generated On: 09 Jun 2021 14:48:59

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[Participant ID](#)

US3032115

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

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US3032115

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 28 Sep 2020 16:59:27

Generated On: 09 Jun 2021 14:48:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	06 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

US3032115

Folder: Screening

Form: Demographics

Data signed: (b) (4) 20 Nov 2020 16:29:24

Generated On: 09 Jun 2021 14:48:59

Date of Birth (MMM yyyy)	(b) (6)	1960
Age		60
Age Units		YEARS
Age (Derived)		60
Sex	Female	<input checked="" type="radio"/>
	Male	<input type="radio"/>
Ethnicity	Hispanic or Latino	<input type="radio"/>
	Not Hispanic or Latino	<input type="radio"/>
	Not Reported	<input checked="" type="radio"/>
	Unknown	<input type="radio"/>
Race (Check All That Apply)		
White		False
Black		False
Asian		False
American Indian or Alaska Native		False
Native Hawaiian or other Pacific Islander		True
Other		False
If race is Other, specify _____		
Unknown		False
Not reported		False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 28 Sep 2020 16:59:27

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Date of Informed Consent ( <i>dd MMM yyyy</i> )	06 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input checked="" type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3032115

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 28 Sep 2020 16:59:27

Generated On: 09 Jun 2021 14:48:59

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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) 28 Sep 2020 16:59:27

Generated On: 09 Jun 2021 14:48:59

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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) 06 Apr 2021 15:33:21

Generated On: 09 Jun 2021 14:48:59

Condition	MYOCARDIAL INFRACTION
Start date (dd MMM yyyy)	UN UNK 2013
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 2013
Start Year (derived)	2013
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 06 Apr 2021 15:33:21

Generated On: 09 Jun 2021 14:48:59

Condition	CEREBROVASCULAR ACCIDENT
Start date (dd MMM yyyy)	UN UNK 2013
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2013
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	JAN 2013
Stop Year (derived)	2013

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 06 Apr 2021 15:33:21

Generated On: 09 Jun 2021 14:48:59

Condition	HYSTERECTOMY
Start date (dd MMM yyyy)	UN UNK 1984
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 1984
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1984
Start Year (derived)	1984
Stop Month and Year (derived)	JAN 1984
Stop Year (derived)	1984

US3032115

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 06 Apr 2021 15:33:21

Generated On: 09 Jun 2021 14:48:59

Condition	ALLERGY TO ALCOHOL, RASH
Start date (dd MMM yyyy)	UN UNK 1983
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 1983
Start Year (derived)	1983
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 06 Apr 2021 15:33:21

Generated On: 09 Jun 2021 14:48:59

Condition	POSTMENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 1984
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 1984
Start Year (derived)	1984
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 06 Apr 2021 15:33:21

Generated On: 09 Jun 2021 14:48:59

Condition	BROKEN TAILBONE
Start date (dd MMM yyyy)	05 AUG 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	05 AUG 2019
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2019
Start Year (derived)	2019
Stop Month and Year (derived)	AUG 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 06 Apr 2021 15:33:21

Generated On: 09 Jun 2021 14:48:59

Condition	BACK PAIN-LOWER LUMBAR
Start date (dd MMM yyyy)	05 AUG 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)	AUG 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 06 Apr 2021 15:33:21

Generated On: 09 Jun 2021 14:48:59

Condition	FRACTURED VERTEBRAE-LUMBAR
Start date (dd MMM yyyy)	05 AUG 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	05 AUG 2019
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2019
Start Year (derived)	2019
Stop Month and Year (derived)	AUG 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 06 Apr 2021 15:33:21

Generated On: 09 Jun 2021 14:48:59

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2013
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 2013
Start Year (derived)	2013
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 06 Apr 2021 15:33:21

Generated On: 09 Jun 2021 14:48:59

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

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 06 Apr 2021 15:33:21

Generated On: 09 Jun 2021 14:48:59

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

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 06 Apr 2021 15:33:21

Generated On: 09 Jun 2021 14:48:59

Condition	RECURRING MISCARRIAGES
Start date (dd MMM yyyy)	UN UNK 1984
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 1984
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1984
Start Year (derived)	1984
Stop Month and Year (derived)	JAN 1984
Stop Year (derived)	1984

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 06 Apr 2021 15:33:21

Generated On: 09 Jun 2021 14:48:59

Condition	AORTIC ANEURYSM
Start date (dd MMM yyyy)	UN UNK 2013
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2013
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	JAN 2013
Stop Year (derived)	2013

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 06 Apr 2021 15:33:21

Generated On: 09 Jun 2021 14:48:59

Condition	HYPERCHOLESTEROLEMIA
Start date (dd MMM yyyy)	UN UNK 2012
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 2012
Start Year (derived)	2012
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 06 Apr 2021 15:33:21

Generated On: 09 Jun 2021 14:48:59

Condition	PAROXYSMAL ATRIAL FIBRILLATION
Start date (dd MMM yyyy)	UN UNK 2007
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 2007
Start Year (derived)	2007
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 06 Apr 2021 15:33:21

Generated On: 09 Jun 2021 14:48:59

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

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 06 Apr 2021 15:33:21

Generated On: 09 Jun 2021 14:48:59

Condition	PULMONARY EMBOLISM OF LEFT LUNG
Start date (dd MMM yyyy)	UN UNK 2008
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 2008
Start Year (derived)	2008
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 06 Apr 2021 15:33:21

Generated On: 09 Jun 2021 14:48:59

Condition	INSOMNIA
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 (19)

Data signed: (b) (4) 06 Apr 2021 15:33:21

Generated On: 09 Jun 2021 14:48:59

Condition	SENSORY NEUROPATHY OF RIGHT ARM, NECK, AND HAND
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 (20)

Data signed: (b) (4) 06 Apr 2021 15:33:21

Generated On: 09 Jun 2021 14:48:59

Condition	VISION CHANGES
Start date (dd MMM yyyy)	UN UNK 2013
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 2013
Start Year (derived)	2013
Stop Month and Year (derived)	
Stop Year (derived)	

US3032115

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 16 Dec 2020 20:07:22

Generated On: 09 Jun 2021 14:48:59

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	6 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	11:15 (24 HR)
Vital Signs Date and Time (derived)	6 AUG 2020 11:15
Height ( <i>xxx.x</i> )	154.9 cm
Weight ( <i>xxx.x</i> )	72.1 kg
BMI ( <i>xxx.x</i> )	30.04917 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)	

US3032115

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 28 Sep 2020 16:59:27

Generated On: 09 Jun 2021 14:48:59

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

6 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) 28 Sep 2020 16:59:27

Generated On: 09 Jun 2021 14:48:59

Date of assessment (dd MMM yyyy) 6 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 UNK 1984

Date of surgery unknown False

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

Date of last menstruation unknown False

US3032115

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 28 Sep 2020 16:59:27

Generated On: 09 Jun 2021 14:48:59

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☒

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**Specify**

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

**No Risk Identified** False

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 28 Sep 2020 16:59:27

Generated On: 09 Jun 2021 14:48:59

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



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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 28 Sep 2020 16:59:27

Generated On: 09 Jun 2021 14:48:59

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

Visit date (dd MMM yyyy)	06 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT1
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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 06 Apr 2021 15:33:21

Generated On: 09 Jun 2021 14:48:59

What was the date of randomization? (dd MMM yyyy) 06 AUG 2020

What was the participant's randomization number? 101479

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Oct 2020 13:47:13

Generated On: 09 Jun 2021 14:48:59

Height	ND - Not Done
Weight	ND - Not Done

US3032115

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Oct 2020 13:47:13

Generated On: 09 Jun 2021 14:48:59

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)	6 AUG 2020
Time of assessment (00:00-23:59)	11:15 (24 HR)
Vital Signs Date and Time (derived)	6 AUG 2020 11:15
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	146 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 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 Oct 2020 13:47:13

Generated On: 09 Jun 2021 14:48:59

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)	6 AUG 2020
Time of assessment (00:00-23:59)	13:15 (24 HR)
Vital Signs Date and Time (derived)	6 AUG 2020 13:15
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 28 Sep 2020 16:59:27

Generated On: 09 Jun 2021 14:48:59

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

6 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) 28 Sep 2020 16:59:27

Generated On: 09 Jun 2021 14:48:59

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) 06 AUG 2020

What was the treatment time? (00:00-23:59) 12:45 (24 HR)

Treatment Date and Time (derived) 06 AUG 2020 12:45

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) 28 Sep 2020 16:59:27

Generated On: 09 Jun 2021 14:48:59

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

6 AUG 2020

Collection time (00:00-23:59)

12:07 (24 HR)

Collection date and time (derived)

6 AUG 2020 12:07



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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 28 Sep 2020 16:59:27

Generated On: 09 Jun 2021 14:48:59

Collection date (dd MMM yyyy)			6 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:50	6 AUG 2020 11:50
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 16:59:27

Generated On: 09 Jun 2021 14:48:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032115

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:48:59

**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

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 AUG 2020 13:16

PC Open Date & Time

06 AUG 2020 13:05

PC Close Date & Time

06 AUG 2020 15:35

US3032115

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:48:59

**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

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

06 AUG 2020 16:30

PC Close Date & Time

07 AUG 2020 11:59

US3032115

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:48:59

**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

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 AUG 2020 20:19

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3032115

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:48:59

**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

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 AUG 2020 23:46

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3032115

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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

09 AUG 2020 18:40

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3032115

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:48:59

**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

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 AUG 2020 06:33

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59



US3032115

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:48:59

**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

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 AUG 2020 22:14

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3032115

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:48:59

**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.

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 AUG 2020 21:17

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3032115

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:48:59

**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

06 AUG 2020 13:16

PC Open Date & Time

06 AUG 2020 13:05

PC Close Date & Time

06 AUG 2020 15:35

US3032115

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

06 AUG 2020 16:30

PC Close Date & Time

07 AUG 2020 11:59

US3032115

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

07 AUG 2020 20:20

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3032115

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:48:59

**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

08 AUG 2020 23:47

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3032115

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:48:59

**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

09 AUG 2020 18:40

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3032115

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

11 AUG 2020 06:33

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59



US3032115

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:48:59

**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

11 AUG 2020 22:15

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3032115

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:48:59

**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

12 AUG 2020 21:17

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:48:59

**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 ☐

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:48:59

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

No ☒

Yes ☐

PC Time stamp	06 AUG 2020 13:17
PC Open Date & Time	06 AUG 2020 13:05
PC Close Date & Time	06 AUG 2020 15:35

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:48:59

**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 ☐

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:48:59

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

06 AUG 2020 16:30

PC Close Date & Time

07 AUG 2020 11:59

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:48:59

**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 ☒

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:48:59

Yes <input type="checkbox"/>	
PC Time stamp	07 AUG 2020 20:21
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59



US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

DAY 3

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:48:59

Yes <input type="checkbox"/>	
PC Time stamp	08 AUG 2020 23:47
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:48:59

**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 ☒

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:48:59

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 18:41
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:48:59

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:48:59

Yes <input type="checkbox"/>	
PC Time stamp	11 AUG 2020 06:34
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:48:59

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 ☒

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:48:59

Yes <input type="checkbox"/>	
PC Time stamp	11 AUG 2020 22:15
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59



US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

DAY 7

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:48:59

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 21:18
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3032115

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 28 Sep 2020 16:59:27

Generated On: 09 Jun 2021 14:48:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3032115

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 16:59:27

Generated On: 09 Jun 2021 14:48:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032115

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 28 Sep 2020 16:59:27

Generated On: 09 Jun 2021 14:48:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3032115

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 16:59:27

Generated On: 09 Jun 2021 14:48:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032115

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 20 Nov 2020 16:29:24

Generated On: 09 Jun 2021 14:48:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3032115

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 16:59:27

Generated On: 09 Jun 2021 14:48:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3032115

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 28 Sep 2020 16:59:27

Generated On: 09 Jun 2021 14:48:59

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

US3032115

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Sep 2020 16:59:27

Generated On: 09 Jun 2021 14:48:59

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)	03 SEP 2020
Time of assessment (00:00-23:59)	08:41 (24 HR)
Vital Signs Date and Time (derived)	03 SEP 2020 08:41
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3032115

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Sep 2020 16:59:27

Generated On: 09 Jun 2021 14:48:59

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)	03 SEP 2020
Time of assessment (00:00-23:59)	10:54 (24 HR)
Vital Signs Date and Time (derived)	03 SEP 2020 10:54
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3032115

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Sep 2020 16:59:27

Generated On: 09 Jun 2021 14:48:59

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

03 SEP 2020

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

US3032115

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 28 Sep 2020 16:59:27

Generated On: 09 Jun 2021 14:48:59

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) 03 SEP 2020

What was the treatment time? (00:00-23:59) 10:21 (24 HR)

Treatment Date and Time (derived) 03 SEP 2020 10:21

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

US3032115

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Sep 2020 16:59:27

Generated On: 09 Jun 2021 14:48:59

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

03 SEP 2020

Collection time (00:00-23:59)

09:35 (24 HR)

Collection date and time (derived)

03 SEP 2020 09:35

US3032115

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 28 Sep 2020 16:59:27

Generated On: 09 Jun 2021 14:48:59

Collection date (dd MMM yyyy)			03 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:57	03 SEP 2020 08:57
Nasopharyngeal Swab 2	No		

US3032115

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 16:59:27

Generated On: 09 Jun 2021 14:48:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3032115

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:48:59

**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

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 10:54

PC Open Date & Time

03 SEP 2020 10:41

PC Close Date & Time

03 SEP 2020 13:11

US3032115

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.7 °F

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

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

PC Time Stamp	03 SEP 2020 17:34
PC Open Date & Time	03 SEP 2020 14:06
PC Close Date & Time	04 SEP 2020 11:59

US3032115

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:48:59

**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

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 18:58

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3032115

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:48:59

**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

98.7 °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

06 SEP 2020 06:25

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3032115

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 22:21

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3032115

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:48:59

**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

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 07:35

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3032115

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 18:32

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3032115

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:48:59

**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

98.8 °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

09 SEP 2020 18:26

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59



US3032115

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:48:59

**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

03 SEP 2020 10:54

PC Open Date & Time

03 SEP 2020 10:41

PC Close Date & Time

03 SEP 2020 13:11

US3032115

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:48:59

**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

03 SEP 2020 17:35

PC Open Date & Time

03 SEP 2020 14:06

PC Close Date & Time

04 SEP 2020 11:59

US3032115

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:48:59

**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)

508

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

04 SEP 2020 19:01

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3032115

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:48:59

**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)

48

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

06 SEP 2020 06:26

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3032115

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:48:59

**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

06 SEP 2020 22:22

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3032115

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:48:59

**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

08 SEP 2020 07:36

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3032115

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:48:59

**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

08 SEP 2020 18:33

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3032115

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:48:59

**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

09 SEP 2020 18:26

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59



US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:48:59

**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 ☐

US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:48:59

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

No ☒

Yes ☐

PC Time stamp	03 SEP 2020 10:55
PC Open Date & Time	03 SEP 2020 10:41
PC Close Date & Time	03 SEP 2020 13:11

US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:48:59

**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 ☐

US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:48:59

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

No ☒

Yes ☐

PC Time stamp	03 SEP 2020 17:35
PC Open Date & Time	03 SEP 2020 14:06
PC Close Date & Time	04 SEP 2020 11:59

US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:48:59

**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 ☒

US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:48:59

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 19:02
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

DAY 3

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:48:59

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 06:27
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59



US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:48:59

**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 2802

EAB) (1725)

US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:48:59

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 22:22
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

DAY 5

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:48:59

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 07:37
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:48:59

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:48:59

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 18:33
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:48:59

**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 ☒

US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:48:59

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 18:27
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59



US3032115

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 28 Sep 2020 16:59:27

Generated On: 09 Jun 2021 14:48:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3032115

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 16:59:27

Generated On: 09 Jun 2021 14:48:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032115

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 28 Sep 2020 16:59:27

Generated On: 09 Jun 2021 14:48:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3032115

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 16:59:27

Generated On: 09 Jun 2021 14:48:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032115

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 08 Oct 2020 15:22:03

Generated On: 09 Jun 2021 14:48:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3032115

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 08 Oct 2020 15:22:03

Generated On: 09 Jun 2021 14:48:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032115

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 08 Oct 2020 15:22:03

Generated On: 09 Jun 2021 14:48:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 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

US3032115

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Oct 2020 15:22:03

Generated On: 09 Jun 2021 14:48:59

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	8 OCT 2020
Time of assessment (00:00-23:59)	08:00 (24 HR)
Vital Signs Date and Time (derived)	8 OCT 2020 08:00
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



US3032115

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Oct 2020 15:22:03

Generated On: 09 Jun 2021 14:48:59

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

8 OCT 2020

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

US3032115

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Oct 2020 15:22:03

Generated On: 09 Jun 2021 14:48:59

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	8 OCT 2020
Collection time (00:00-23:59)	08:17 (24 HR)
Collection date and time (derived)	8 OCT 2020 08:17

US3032115

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 08 Oct 2020 15:22:03

Generated On: 09 Jun 2021 14:48:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032115

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

<b>TIMEPOINT</b>	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 OCT 2020 15:15:21
Patient Cloud Open Date & Time	06 OCT 2020 00:01
Patient Cloud Close Date & Time	10 OCT 2020 23:59

US3032115

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**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 13 OCT 2020 15:30:32

Patient Cloud Open Date & Time 13 OCT 2020 00:01

Patient Cloud Close Date & Time 17 OCT 2020 23:59

US3032115

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**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

20 OCT 2020 07:04:10

Patient Cloud Open Date & Time

20 OCT 2020 00:01

Patient Cloud Close Date & Time

24 OCT 2020 23:59

US3032115

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 NOV 2020 09:22:51

Patient Cloud Open Date & Time

03 NOV 2020 00:01

Patient Cloud Close Date & Time

07 NOV 2020 23:59

US3032115

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

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	10 NOV 2020 12:09:54
Patient Cloud Open Date & Time	10 NOV 2020 00:01
Patient Cloud Close Date & Time	14 NOV 2020 23:59



US3032115

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

DAY 106

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 NOV 2020 08:11:14

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 NOV 2020 09:50:10

Patient Cloud Open Date & Time

21 NOV 2020 00:01

Patient Cloud Close Date & Time

25 NOV 2020 23:59

US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**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

30 NOV 2020 11:43:16

Patient Cloud Open Date & Time

28 NOV 2020 00:01

Patient Cloud Close Date & Time

02 DEC 2020 23:59

US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**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

05 DEC 2020 08:13:53

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 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"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	True
Chills	True
Cough	True
Shortness of breath	True
Difficulty breathing	True
Fatigue	True
Muscle aches	True
Body aches	True
Headache	True
New loss of taste	True
New loss of smell	True
Sore throat	True
Congestion	False
Runny nose	True
Nausea	True
Vomiting	False
Diarrhea	True
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

Please contact your study clinic immediately. Click below to confirm that you have read this 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	13 DEC 2020 13:32:58
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**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

21 DEC 2020 05:49:13

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

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 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	27 DEC 2020 10:53:15
Patient Cloud Open Date & Time	26 DEC 2020 00:01
Patient Cloud Close Date & Time	30 DEC 2020 23:59



US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 JAN 2021 20:31:27

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 JAN 2021 10:13:44

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 JAN 2021 08:13:23

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**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

25 JAN 2021 16:23:51

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 JAN 2021 22:41:42
Patient Cloud Open Date & Time	30 JAN 2021 00:01
Patient Cloud Close Date & Time	03 FEB 2021 23:59

US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 FEB 2021 05:51:25

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**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

14 FEB 2021 08:44:54

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59

US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 FEB 2021 05:56:18

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59



US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**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

27 FEB 2021 16:45:46

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 MAR 2021 20:42:11

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 MAR 2021 17:42:19

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**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

20 MAR 2021 08:54:53

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 MAR 2021 09:04:07

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 APR 2021 09:59:42

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**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

10 APR 2021 14:43:06

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

<b>TIMEPOINT</b>	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 <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 APR 2021 10:15:37
Patient Cloud Open Date & Time	17 APR 2021 00:01
Patient Cloud Close Date & Time	21 APR 2021 23:59



US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	25 APR 2021 20:03:55
Patient Cloud Open Date & Time	24 APR 2021 00:01
Patient Cloud Close Date & Time	28 APR 2021 23:59

US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

DAY 271

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 MAY 2021 07:19:35

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**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°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 ☐

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

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

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[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

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US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

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

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

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

15 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

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US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**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 ☐

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

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

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[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

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US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**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 ☐

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

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

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

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

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[Patient Cloud Open Date & Time](#)

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05 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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09 JUN 2021 23:59

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US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**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 ☐

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

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

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[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

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US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

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"/>

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

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



US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

DAY 327

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

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

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

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

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

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

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

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

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

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

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

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

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[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

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US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

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

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

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

US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**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 ☐  
Yes ☐

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

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

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



US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**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 ☐

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

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

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[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

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US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**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 ☐

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

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

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[Patient Cloud Open Date & Time](#)

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31 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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04 AUG 2021 23:59

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US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

DAY 369

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

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

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[Patient Cloud Open Date & Time](#)

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07 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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11 AUG 2021 23:59

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US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**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 ☐

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	14 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	18 AUG 2021 23:59
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US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

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 <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"/>

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

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

US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

DAY 390

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

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

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

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

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

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

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

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

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

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

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[Patient Cloud Open Date & Time](#)

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28 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 SEP 2021 23:59

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US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**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 ☐

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

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

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[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

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US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

DAY 404

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

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

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

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

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

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

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

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

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

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

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[Patient Cloud Open Date & Time](#)

11 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

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US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

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

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

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

US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**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 ☐

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

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

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[Patient Cloud Open Date & Time](#)

25 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

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US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**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 ☐

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

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

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**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 ☐

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

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

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[Patient Cloud Open Date & Time](#)

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09 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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13 OCT 2021 23:59

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US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**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 ☐

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

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

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

DAY 446

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	23 OCT 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	27 OCT 2021 23:59
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US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**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 ☐

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

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

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

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"/>

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

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

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[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

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US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**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 ☐ Yes ☐

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

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

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

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[Patient Cloud Open Date & Time](#)

13 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

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US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**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 ☐

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

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

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[Patient Cloud Open Date & Time](#)

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20 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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24 NOV 2021 23:59

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US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**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 ☐

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

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

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

DAY 488

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

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

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

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

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

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

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

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

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

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

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[Patient Cloud Open Date & Time](#)

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04 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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08 DEC 2021 23:59

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US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**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°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 ☐

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

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

US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**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 ☐

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

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

18 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59

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US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**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 ☐

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

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

US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**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 ☐

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	05 JAN 2022 23:59



US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**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 ☐

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

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

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

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

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

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

15 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

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US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**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 ☐

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

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

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[Patient Cloud Open Date & Time](#)

22 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

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US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

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

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

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

29 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

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US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**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 ☐

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

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

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[Patient Cloud Open Date & Time](#)

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05 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 FEB 2022 23:59

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US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**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 ☐

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

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

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[Patient Cloud Close Date & Time](#)

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16 FEB 2022 23:59

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US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**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 ☐

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

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

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[Patient Cloud Close Date & Time](#)

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23 FEB 2022 23:59

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US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**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 ☐

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

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

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[Patient Cloud Open Date & Time](#)

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26 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 MAR 2022 23:59

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US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**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 ☐

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

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

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[Patient Cloud Open Date & Time](#)

05 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

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US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**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 ☐

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

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

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[Patient Cloud Close Date & Time](#)

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16 MAR 2022 23:59

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US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**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 ☐

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

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

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[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

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US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

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"/>

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

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

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59



US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

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"/>

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

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

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[Patient Cloud Open Date & Time](#)

02 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

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US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

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"/>

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

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

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

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

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

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

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[Patient Cloud Open Date & Time](#)

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16 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 APR 2022 23:59

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US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

DAY 628

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

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

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

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

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

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

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

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

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	23 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 APR 2022 23:59



US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**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 ☐

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

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

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[Patient Cloud Open Date & Time](#)

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30 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 MAY 2022 23:59

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US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

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

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

DAY 649

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

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

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

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

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

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

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

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

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

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

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[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

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US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

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

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[Patient Cloud Open Date & Time](#)

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21 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 MAY 2022 23:59

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US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**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 ☐

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

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

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[Patient Cloud Open Date & Time](#)

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28 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 JUN 2022 23:59

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US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**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 ☐

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

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

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[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

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US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**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 ☐

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	11 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 JUN 2022 23:59

US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**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 ☐

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

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

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[Patient Cloud Open Date & Time](#)

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18 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 JUN 2022 23:59

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US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

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

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

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

US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**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 ☐

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

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

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[Patient Cloud Close Date & Time](#)

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06 JUL 2022 23:59

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US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**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 ☐

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**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°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 ☐

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 JUL 2022 23:59



US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

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"/>

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

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

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

DAY 726

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

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

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

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

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

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

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

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

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

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

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[Patient Cloud Open Date & Time](#)

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30 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 AUG 2022 23:59

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US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**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 ☐

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

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

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

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"/>

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

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

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[Patient Cloud Open Date & Time](#)

13 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

17 AUG 2022 23:59

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US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**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 ☐

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

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

US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**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 ☐

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

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

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[Patient Cloud Open Date & Time](#)

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27 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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31 AUG 2022 23:59

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US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

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

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	03 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	07 SEP 2022 23:59

US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

DAY 768

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

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

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

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

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

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

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

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

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

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



US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**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 ☐

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

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

17 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

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US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**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 ☐

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

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

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[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

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US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**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 ☐

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

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

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[Patient Cloud Open Date & Time](#)

01 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

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US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

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

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[Patient Cloud Open Date & Time](#)

08 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

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US3032115

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 14:48:59

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		27 FEB 2021 16:46:04

US3032115

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 28 Oct 2020 15:25:04

Generated On: 09 Jun 2021 14:48:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3032115

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 28 Oct 2020 15:25:04

Generated On: 09 Jun 2021 14:48:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032115

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 14 Apr 2021 19:20:03

Generated On: 09 Jun 2021 14:48:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3032115

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 07 Jan 2021 19:16:01

Generated On: 09 Jun 2021 14:48:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032115

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 07 Jan 2021 19:16:01

Generated On: 09 Jun 2021 14:48:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3032115

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 07 Jan 2021 19:16:01

Generated On: 09 Jun 2021 14:48:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032115

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Feb 2021 19:39:23

Generated On: 09 Jun 2021 14:48:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

03 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3032115

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Feb 2021 19:39:23

Generated On: 09 Jun 2021 14:48:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032115

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 10 Mar 2021 15:21:18

Generated On: 09 Jun 2021 14:48:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3032115

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 06 Apr 2021 15:33:21

Generated On: 09 Jun 2021 14:48:59

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) \_\_\_\_\_

US3032115

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 10 Mar 2021 15:21:18

Generated On: 09 Jun 2021 14:48:59

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.*

US3032115

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 10 Mar 2021 15:21:18

Generated On: 09 Jun 2021 14:48:59

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

4 MAR 2021

Collection time (00:00-23:59)

10:48 (24 HR)

Collection date and time (derived)

4 MAR 2021 10:48

US3032115

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 15:21:18

Generated On: 09 Jun 2021 14:48:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032115

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 19 Apr 2021 15:26:28

Generated On: 09 Jun 2021 14:48:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3032115

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 19 Apr 2021 15:26:28

Generated On: 09 Jun 2021 14:48:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3032115

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:59

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*

**US3032115**

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

**Form: Continuing**

**Generated On: 09 Jun 2021 14:48:59**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: COVID-19 Contact

Data signed: (b) (4) 10 Dec 2020 16:21:15

Generated On: 09 Jun 2021 14:48:59

Date of Contact	8 DEC 2020
Time of Contact	11:15
Date and Time of Contact (derived)	8 DEC 2020 11:15
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input checked="" type="checkbox"/></div> <div>Safety Call<input type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 16 Dec 2020 20:07:22

Generated On: 09 Jun 2021 14:48:59

Symptom Day

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

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 16 Dec 2020 20:07:22

Generated On: 09 Jun 2021 14:48:59

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	5 DEC 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 16 Dec 2020 20:07:22

Generated On: 09 Jun 2021 14:48:59

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

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 16 Dec 2020 20:07:22

Generated On: 09 Jun 2021 14:48:59

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

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 16 Dec 2020 20:07:22

Generated On: 09 Jun 2021 14:48:59

Symptom Day

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



US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 16 Dec 2020 20:07:22

Generated On: 09 Jun 2021 14:48:59

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

Date	6 DEC 2020
------	------------

Assessment Not Done	True
---------------------	------

O2 Saturation	
---------------	--

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

Temperature	
-------------	--

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 16 Dec 2020 20:07:22

Generated On: 09 Jun 2021 14:48:59

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 16 Dec 2020 20:07:22

Generated On: 09 Jun 2021 14:48:59

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

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 16 Dec 2020 20:07:22

Generated On: 09 Jun 2021 14:48:59

Symptom Day

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

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 16 Dec 2020 20:07:22

Generated On: 09 Jun 2021 14:48:59

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	7 DEC 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 16 Dec 2020 20:07:22

Generated On: 09 Jun 2021 14:48:59

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

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 16 Dec 2020 20:07:22

Generated On: 09 Jun 2021 14:48:59

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

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 16 Dec 2020 20:07:22

Generated On: 09 Jun 2021 14:48:59

Symptom Day

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



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Form: Symptom Log (4)

Data signed: (b) (4) 16 Dec 2020 20:07:22

Generated On: 09 Jun 2021 14:48:59

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	8 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 16 Dec 2020 20:07:22

Generated On: 09 Jun 2021 14:48:59

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 16 Dec 2020 20:07:22

Generated On: 09 Jun 2021 14:48:59

Nasal Congestion

None ☐  
Mild ☐  
Moderate ☒  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐  
Mild ☐  
Moderate ☐  
Severe ☒  
Not Done ☐

Nausea

None ☐  
Mild ☐  
Moderate ☒  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☐  
Mild ☐  
Moderate ☐  
Severe ☒  
Not Done ☐

Sore Throat

None ☐  
Mild ☐  
Moderate ☒  
Severe ☐  
Not Done ☐

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Form: Symptom Log (5)

Data signed: (b) (4) 16 Dec 2020 20:07:22

Generated On: 09 Jun 2021 14:48:59

Symptom Day

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

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Form: Symptom Log (5)

Data signed: (b) (4) 16 Dec 2020 20:07:22

Generated On: 09 Jun 2021 14:48:59

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	9 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	36.3 C	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input checked="" type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 16 Dec 2020 20:07:22

Generated On: 09 Jun 2021 14:48:59

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

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Form: Symptom Log (5)

Data signed: (b) (4) 16 Dec 2020 20:07:22

Generated On: 09 Jun 2021 14:48:59

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

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Form: Symptom Log (6)

Data signed: (b) (4) 16 Dec 2020 20:07:22

Generated On: 09 Jun 2021 14:48:59

Symptom Day

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



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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 16 Dec 2020 20:07:22

Generated On: 09 Jun 2021 14:48:59

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

Date	10 DEC 2020
------	-------------

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

O2 Saturation	96 %
---------------	------

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

Temperature	101.3 F
-------------	---------

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 16 Dec 2020 20:07:22

Generated On: 09 Jun 2021 14:48:59

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

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 16 Dec 2020 20:07:22

Generated On: 09 Jun 2021 14:48:59

Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☐  
Mild ☐  
Moderate ☒  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☐  
Mild ☐  
Moderate ☒  
Severe ☐  
Not Done ☐

Sore Throat

None ☐  
Mild ☐  
Moderate ☒  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 16 Dec 2020 20:07:22

Generated On: 09 Jun 2021 14:48:59

Symptom Day

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

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 16 Dec 2020 20:07:22

Generated On: 09 Jun 2021 14:48:59

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	11 DEC 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	99.0 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 16 Dec 2020 20:07:22

Generated On: 09 Jun 2021 14:48:59

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

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 16 Dec 2020 20:07:22

Generated On: 09 Jun 2021 14:48:59

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

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 16 Dec 2020 20:07:22

Generated On: 09 Jun 2021 14:48:59

Symptom Day

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



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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 16 Dec 2020 20:07:22

Generated On: 09 Jun 2021 14:48:59

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	12 DEC 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 16 Dec 2020 20:07:22

Generated On: 09 Jun 2021 14:48:59

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

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 16 Dec 2020 20:07:22

Generated On: 09 Jun 2021 14:48:59

Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☐  
Mild ☐  
Moderate ☒  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☐  
Mild ☐  
Moderate ☒  
Severe ☐  
Not Done ☐

Sore Throat

None ☐  
Mild ☐  
Moderate ☒  
Severe ☐  
Not Done ☐

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 16 Dec 2020 20:07:22

Generated On: 09 Jun 2021 14:48:59

Symptom Day

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

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 16 Dec 2020 20:07:22

Generated On: 09 Jun 2021 14:48:59

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	13 DEC 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
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EAB) (1725)		

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 16 Dec 2020 20:07:22

Generated On: 09 Jun 2021 14:48:59

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

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 16 Dec 2020 20:07:22

Generated On: 09 Jun 2021 14:48:59

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

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 16 Dec 2020 20:07:22

Generated On: 09 Jun 2021 14:48:59

Symptom Day

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



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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 16 Dec 2020 20:07:22

Generated On: 09 Jun 2021 14:48:59

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	14 DEC 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 16 Dec 2020 20:07:22

Generated On: 09 Jun 2021 14:48:59

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

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 16 Dec 2020 20:07:22

Generated On: 09 Jun 2021 14:48:59

Nasal Congestion

None ☐  
Mild ☐  
Moderate ☒  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☐  
Mild ☐  
Moderate ☒  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 10 Dec 2020 16:21:15

Generated On: 09 Jun 2021 14:48:59

Date of Visit 9 DEC 2020

Was the Subject Tested For SARS-CoV-2 by RT-PCR? Yes ☒  
No ☐

Did Subject Test Positive For SARS-CoV-2 by RT-PCR? Yes ☐  
No ☒

Date of Test 9 DEC 2020

Type of Test Performed Nasopharyngeal Swab ☒  
Nasal Swab ☐  
Saliva Test ☐  
Other ☐

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

Was this diagnostic test performed at a lab other than the Study Central Lab? Yes ☐  
No ☒

If yes, provide lab information below

Lab/ Institution Test Performed \_\_\_\_\_

CLIA Certified? Yes ☐  
No ☐

COVID-19 Positive (CSA Programming Field Only) 0

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 10 Dec 2020 16:21:15

Generated On: 09 Jun 2021 14:48:59

---

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

---

US3032115

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 30 Jan 2021 16:47:57

Generated On: 09 Jun 2021 14:48:59

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	11 DEC 2020
Day 5	Yes	14 DEC 2020
Day 7	Yes	15 DEC 2020
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3032115

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 10 Dec 2020 16:21:15

Generated On: 09 Jun 2021 14:48:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	09 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3032115

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 10 Dec 2020 16:21:15

Generated On: 09 Jun 2021 14:48:59

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	9 DEC 2020
Time of assessment ( <i>00:00-23:59</i> )	09:09 (24 HR)
Vital Signs Date and Time (derived)	9 DEC 2020 09:09
Height ( <i>xxx.x</i> )	154.9 cm
Weight ( <i>xxx.x</i> )	72 kg
Temperature ( <i>xxx.x</i> )	36.3 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	85 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	22 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



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Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 10 Dec 2020 16:21:15

Generated On: 09 Jun 2021 14:48:59

---

Was the physical examination performed?

Yes ☒

No ☐

---

Date of examination (dd MMM yyyy)

9 DEC 2020

---

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

---

US3032115

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 10 Dec 2020 16:21:15

Generated On: 09 Jun 2021 14:48:59

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

Yes ☐

No ☒

NA (COVID-19 Negative) ☐

Date of Collection

US3032115

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

Form: Visit Date

Data signed: (b) (4) 30 Jan 2021 16:48:04

Generated On: 09 Jun 2021 14:48:59

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

Visit date (dd MMM yyyy)	28 JAN 2021
--------------------------	-------------

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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US3032115

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

Form: Unblinding

Data signed: (b) (4) 18 Mar 2021 21:11:09

Generated On: 09 Jun 2021 14:48:59

Date of updated informed consent (dd MMM yyyy) 28 JAN 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 28 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

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

US3032115

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 30 Jan 2021 16:48:04

Generated On: 09 Jun 2021 14:48:59

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

28 JAN 2021

Collection time (00:00-23:59)

10:00 (24 HR)

Collection date and time (derived)

28 JAN 2021 10:00

US3032115

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 30 Jan 2021 16:48:04

Generated On: 09 Jun 2021 14:48:59

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

Collection date (dd MMM yyyy)	28 JAN 2021
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Collection time (00:00 - 23:59)	09:29
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Collection Date and Time (derived)	28 JAN 2021 09:29
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US3032115

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 10 Dec 2020 16:21:15

Generated On: 09 Jun 2021 14:48:59

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Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3032115

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 06 Apr 2021 15:33:21

Generated On: 09 Jun 2021 14:48:59

AEID	USA-US032-2021-MRNA-1273-P30 1000001
Adverse event	SEPSIS OF UNKNOWN ORIGIN
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)	21 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	24 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	21 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	24 DEC 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) 06 Apr 2021 15:33:21

Generated On: 09 Jun 2021 14:48:59

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

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 06 Apr 2021 15:33:21

Generated On: 09 Jun 2021 14:48:59

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THE SUBJECT IS CALLED. SHE REPORTS SHE WAS HOSPITALIZED 21 DEC-24 DEC DUE TO SEPSIS OF UNKNOWN ORIGIN. SHE WAS NOT IN THE ICU. SHE CONTINUES TO FEEL UNWELL, BUT IS CURRENTLY AT HOME. MEDICAL RECORDS ARE REQUESTED. SHE WILL INFORM SITE IF THERE ARE ANY OTHER CHANGES. NO QUESTIONS OR CONCERNS. SHE HAS CONTINUED TO TEST NEGATIVE FOR COVID. UPDATE 05 FEB: MEDICAL RECORDS REVIEWED. THE SUBJECTS SYMPTOMS BEGAN 05 DEC 2020. SHE DID HAVE AN ER VISIT ON 09 DEC 2020 AND WAS DISCHARGED HOME WITH NEW MEDICATIONS. HER ILLNESS CONTINUED. SHE WAS SEEN SEVERAL TIMES BY HER PCP AND TOOK MULTIPLE COURSES OF ABX'S AND STEROIDS. ON 21 DEC 2020 SHE AGAIN SOUGHT CARE THROUGH THE ER WHILE EXPERIENCING FEVER, CHILLS, PLEURISY, AND SHORTNESS OF BREATH. HER CT OF CHEST/ABD WAS NEGATIVE. SHE WAS NEGATIVE FOR RSV, COVID, INFLUENZA, ETC. HER LACTIC ACID WAS 1.7, WBC 6.2,

US3032115

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 06 Apr 2021 15:33:21

Generated On: 09 Jun 2021 14:48:59

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AND SHE WAS HYPOTENSIVE.  
SHE WAS ADMITTED TO THE  
HOSPITAL FOR SEPSIS OF  
UNKNOWN ORIGIN. SHE WAS  
NOT IN THE ICU. SHE WAS  
STARTED ON VANCOMYCIN  
AND AZTREONAM. THE  
SUBJECT WAS DISCHARGED 24  
DEC 2020 ONCE MEDICALLY  
STABLE.  
DATES OF NEGATIVE COVID  
TESTING: STUDY COVID TEST:  
09DEC2020, ER RAPID TEST  
10DEC, TEST @ PCP 18DEC,  
RAPID ER TEST 21DEC,  
NEGATIVE ANTIBODY TEST  
22DEC. NEGATIVE  
RESPIRATORY PANEL 22DEC

---

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

---

US3032115

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 06 Apr 2021 15:33:21

Generated On: 09 Jun 2021 14:48:59

AEID

Adverse event

BILATERAL PNEUMONIA

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

5 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

20 DEC 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 06 Apr 2021 15:33:21

Generated On: 09 Jun 2021 14:48:59

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

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 06 Apr 2021 15:33:21

Generated On: 09 Jun 2021 14:48:59

AEID

Adverse event

WORSENING OF HOMOZYGOUS  
FAMILIAL  
HYPERCHOLESTEROLEMIA

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

15 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

16 MAR 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 06 Apr 2021 15:33:21

Generated On: 09 Jun 2021 14:48:59

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

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 28 Sep 2020 16:59:27

Generated On: 09 Jun 2021 14:48:59

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

Yes ☒

No ☐

---

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 14 Apr 2021 19:20:03

Generated On: 09 Jun 2021 14:48:59

Name of Medication PLAVIX CLOPIDOGREL

Prophylaxis Yes ☐  
No ☒

Indication MEDICAL HISTORY: AORTIC ANEURISM

Dose per administration 300

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 14 Apr 2021 19:20:03

Generated On: 09 Jun 2021 14:48:59

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2013
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 (2)

Data signed: (b) (4) 14 Apr 2021 19:20:03

Generated On: 09 Jun 2021 14:48:59

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐  
No ☒

Indication MEDICAL HISTORY: ACID  
REFLUX

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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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 14 Apr 2021 19:20:03

Generated On: 09 Jun 2021 14:48:59

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 14 Apr 2021 19:20:03

Generated On: 09 Jun 2021 14:48:59

Name of Medication TRAMADOL

Prophylaxis Yes ☐  
No ☒

Indication MEDICAL HISTORY: LOWER  
LUMBAR PAIN

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 14 Apr 2021 19:20:03

Generated On: 09 Jun 2021 14:48:59

	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)		05 AUG 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 (4)

Data signed: (b) (4) 14 Apr 2021 19:20:03

Generated On: 09 Jun 2021 14:48:59

Name of Medication LOSARTAN

Prophylaxis Yes ☐  
No ☒

Indication MEDICAL HISTORY:  
HYPERTENSION

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 14 Apr 2021 19:20:03

Generated On: 09 Jun 2021 14:48:59

	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)	UN UNK 2013	
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) 14 Apr 2021 19:20:03

Generated On: 09 Jun 2021 14:48:59

Name of Medication BETAPACE

Prophylaxis Yes ☐  
No ☒

Indication AEORTIC ANEURISM

Dose per administration 80

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 14 Apr 2021 19:20:03

Generated On: 09 Jun 2021 14:48:59

	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 2013	
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) 14 Apr 2021 19:20:03

Generated On: 09 Jun 2021 14:48:59

Name of Medication ALPRAZOLAM

Prophylaxis Yes ☐  
No ☒

Indication MEDICAL HISTORY: ANXIETY

Dose per administration .5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 14 Apr 2021 19:20:03

Generated On: 09 Jun 2021 14:48:59

	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 2012	
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) 14 Apr 2021 19:20:03

Generated On: 09 Jun 2021 14:48:59

Name of Medication AMLODIPINE

Prophylaxis Yes ☐  
No ☒

Indication MEDICAL HISTORY:  
HYPERTENSION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 14 Apr 2021 19:20:03

Generated On: 09 Jun 2021 14:48:59

	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)	UN UNK 2013	
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) 14 Apr 2021 19:20:03

Generated On: 09 Jun 2021 14:48:59

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 (8)

Data signed: (b) (4) 14 Apr 2021 19:20:03

Generated On: 09 Jun 2021 14:48:59

	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 2004	
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) 14 Apr 2021 19:20:03

Generated On: 09 Jun 2021 14:48:59

Name of Medication ISOSORBIDE MONONITRATE ER

Prophylaxis Yes ☐  
No ☒

Indication MEDICAL HISTORY: AORTIC ANEURYSM

Dose per administration 60

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) 14 Apr 2021 19:20:03

Generated On: 09 Jun 2021 14:48:59

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2013
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) 14 Apr 2021 19:20:03

Generated On: 09 Jun 2021 14:48:59

Name of Medication PRAVASTATIN

Prophylaxis Yes ☐  
No ☒

Indication MEDICAL HISTORY:  
HYPERCHOLESTEROLEMIA

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 (10)

Data signed: (b) (4) 14 Apr 2021 19:20:03

Generated On: 09 Jun 2021 14:48:59

	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)	UN	UNK 2012
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) 14 Apr 2021 19:20:03

Generated On: 09 Jun 2021 14:48:59

Name of Medication DEXAMETHASONE

Prophylaxis Yes ☐  
No ☒

Indication BILATERAL PNEUMONIA

Dose per administration 6

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 14 Apr 2021 19:20:03

Generated On: 09 Jun 2021 14:48:59

	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 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		18 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 14 Apr 2021 19:20:03

Generated On: 09 Jun 2021 14:48:59

Name of Medication BENZONATATE

Prophylaxis Yes ☐  
No ☒

Indication BILATERAL PNEUMONIA

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 14 Apr 2021 19:20:03

Generated On: 09 Jun 2021 14:48:59

	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)		9 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		21 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 14 Apr 2021 19:20:03

Generated On: 09 Jun 2021 14:48:59

Name of Medication ALBUTEROL

Prophylaxis Yes ☐  
No ☒

Indication BILATERAL PNEUMONIA

Dose per administration 90

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 14 Apr 2021 19:20:03

Generated On: 09 Jun 2021 14:48:59

	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)		09 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		24 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 14 Apr 2021 19:20:03

Generated On: 09 Jun 2021 14:48:59

Name of Medication LEVOFLOXACIN

Prophylaxis Yes ☐  
No ☒

Indication BILATERAL PNEUMONIA

Dose per administration 750

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 (14)

Data signed: (b) (4) 14 Apr 2021 19:20:03

Generated On: 09 Jun 2021 14:48:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		14 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		21 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input 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 (15)

Data signed: (b) (4) 14 Apr 2021 19:20:03

Generated On: 09 Jun 2021 14:48:59

Name of Medication NORMAL SALINE

Prophylaxis Yes ☐  
No ☒

Indication SEPSIS

Dose per administration 125

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

If dose unit is Other, specify ML/HR

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 CONTINUOUS

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 14 Apr 2021 19:20:03

Generated On: 09 Jun 2021 14:48:59

	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 checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		21 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		24 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 14 Apr 2021 19:20:03

Generated On: 09 Jun 2021 14:48:59

Name of Medication VANCOMYCIN

Prophylaxis Yes ☐  
No ☒

Indication SEPSIS

Dose per administration 1250

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

EVERY 12 HOURS

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 14 Apr 2021 19:20:03

Generated On: 09 Jun 2021 14:48:59

	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)		21 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		24 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>



US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 14 Apr 2021 19:20:03

Generated On: 09 Jun 2021 14:48:59

Name of Medication AZTREONAM

Prophylaxis Yes ☐  
No ☒

Indication SEPSIS

Dose per administration 2000

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

EVERY 8 HOURS

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 14 Apr 2021 19:20:03

Generated On: 09 Jun 2021 14:48:59

	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 checked="" 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)	21 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)		24 DEC 2020
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 14 Apr 2021 19:20:03

Generated On: 09 Jun 2021 14:48:59

Name of Medication LOVENOX (ENOXAPARIN)

Prophylaxis Yes ☐  
No ☒

Indication SEPSIS

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 14 Apr 2021 19:20:03

Generated On: 09 Jun 2021 14:48:59

	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)	21 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	24 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 14 Apr 2021 19:20:03

Generated On: 09 Jun 2021 14:48:59

Name of Medication REPATHA (EVOLOCUMAB)

Prophylaxis Yes ☐  
No ☒

Indication HOMOZYGOUS FAMILIAL  
HYPERCHOLESTEROLEMIA

Dose per administration 420

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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US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 14 Apr 2021 19:20:03

Generated On: 09 Jun 2021 14:48:59

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

US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 18 Mar 2021 21:11:09

Generated On: 09 Jun 2021 14:48:59

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 18 Mar 2021 21:11:09

Generated On: 09 Jun 2021 14:48:59

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
22 DEC 2020	CT OF SOFT TISSUE OF NECK	Adverse Event	
22 DEC 2020	CT ANGIOGRAM OF CHEST	Adverse Event	
22 DEC 2020	CT ABDOMEN/PELVIS	Adverse Event	
22 DEC 2020	INFLUENZA TESTING	Adverse Event	
22 DEC 2020	COVID-19 PCR	Adverse Event	
22 DEC 2020	BLOOD CULTURES	Adverse Event	
22 DEC 2020	LACTIC ACID	Adverse Event	
22 DEC 2020	COVID-19 ANTIBODY	Adverse Event	
22 DEC 2020	PROCALCITONIN	Adverse Event	
22 DEC 2020	D-DIMER	Adverse Event	
22 DEC 2020	TROPONIN	Adverse Event	
22 DEC 2020	HIV TESTING	Adverse Event	
22 DEC 2020	RESPIRATORY VIRAL PANEL	Adverse Event	
22 DEC 2020	FUNGITELL TESTING	Adverse Event	
22 DEC 2020	ASPERGILLUS GALACTOMANNAN TESTING	Adverse Event	
22 DEC 2020	COMPLETE BLOOD COUNT	Adverse Event	
22 DEC 2020	COMPLETE METABOLIC PANEL	Adverse Event	
09 DEC 2020	STUDY-RELATED COVID-19 TEST	Adverse Event	
10 DEC 2020	RAPID COVID-19 TEST	Adverse Event	
18 DEC 2020	COVID-19 PCR TEST	Adverse Event	

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:48:59

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 ☐

US3032115

Folder: SAE USA-US032-2021-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 18 Mar 2021 21:11:09

Generated On: 09 Jun 2021 14:48:59

SAEID	USA-US032-2021-MRNA-1273-P301000001
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	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6

US3032115

Folder: SAE USA-US032-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 18 Mar 2021 21:11:09

Generated On: 09 Jun 2021 14:48:59

SAEID	USA-US032-2021-MRNA-1273-P301000001
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	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	04/JAN/2021 13:28
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3032115

Folder: SAE USA-US032-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 18 Mar 2021 21:11:09

Generated On: 09 Jun 2021 14:48:59

SAEID	USA-US032-2021-MRNA-1273-P301000001
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	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	02/FEB/2021 10:33
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3032115

Folder: SAE USA-US032-2021-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 18 Mar 2021 21:11:09

Generated On: 09 Jun 2021 14:48:59

SAEID	USA-US032-2021-MRNA-1273-P301000001
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	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	09/FEB/2021 08:40
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

US3032115

Folder: SAE USA-US032-2021-MRNA-1273-P301000001

Form: Safety Report Form (4)

Data signed: (b) (4) 18 Mar 2021 21:11:09

Generated On: 09 Jun 2021 14:48:59

SAEID	USA-US032-2021-MRNA-1273-P301000001
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	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	11/FEB/2021 08:46
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

US3032115

Folder: SAE USA-US032-2021-MRNA-1273-P301000001

Form: Safety Report Form (5)

Data signed: (b) (4) 18 Mar 2021 21:11:09

Generated On: 09 Jun 2021 14:48:59

SAEID	USA-US032-2021-MRNA-1273-P301000001
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	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	26/FEB/2021 15:01
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

US3032115

Folder: SAE USA-US032-2021-MRNA-1273-P301000001

Form: Safety Report Form (6)

Data signed: (b) (4) 18 Mar 2021 21:11:09

Generated On: 09 Jun 2021 14:48:59

SAEID	USA-US032-2021-MRNA-1273-P301000001
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	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	17/MAR/2021 12:58
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True



Audit

US3032115 (Prod: Meridian Clinical Research (Norfolk-Nebraska))

**US3032115**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 14:48:59**

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 03:44:31
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered 'US3032115'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 16:25:46

US3032115

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:48:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:11:09
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	06 Aug 2020 17:51:29

US3032115

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:48:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:11:09
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered '06 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 16:25:47

US3032115

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:48:59

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 02:13:03
DataPoint Verified.		17 Dec 2020 20:11:09
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered 'Clinic (Clinic)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	06 Aug 2020 17:51:29

**US3032115**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:48:59**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered 'SCRN'	System	06 Aug 2020 17:51:29

US3032115

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:48:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:11:12
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered '(b) (6) 960'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 16:25:48

US3032115

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:48:59

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:11:12
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered '60'	(b) (4) Linden DeBoer (b) (4) (b) (4)	06 Aug 2020 17:52:02



**US3032115**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:48:59**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered 'YEARS'	System	06 Aug 2020 17:52:02

**US3032115**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:48:59**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered '60'	System	06 Aug 2020 17:52:16

**US3032115**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:48:59**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:11:12
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered 'Female (F)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	06 Aug 2020 17:52:02

US3032115

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:48:59

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:11:12
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:24
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	18 Nov 2020 17:18:38
	(b) (4)	
User entered 'Not Reported (NOT REPORTED)'	Linden DeBoer (b) (4)	18 Nov 2020 17:18:38
reason for change: Data Entry Error	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
	(b) (4)	
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Linden DeBoer (b) (4)	06 Aug 2020 17:52:02
	(b) (4)	

US3032115

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:48:59

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:11:12
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered '0' reason for change: Data Entry Error	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 20:41:41
User entered '1'	(b) (4) Linden DeBoer (b) (4)	06 Aug 2020 17:52:02

US3032115

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:48:59

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:11:12
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	06 Aug 2020 17:52:02

**US3032115**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:48:59**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:11:12
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	06 Aug 2020 17:52:02

US3032115

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:48:59

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:11:12
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	06 Aug 2020 17:52:02



US3032115

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:48:59

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:11:12
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered '1' reason for change: Data Entry Error	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 20:41:41
User entered '0'	(b) (4) Linden DeBoer (b) (4)	06 Aug 2020 17:52:02

**US3032115**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:48:59**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:11:12
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	06 Aug 2020 17:52:02

US3032115

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:48:59

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:11:12
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered empty.	(b) (4)	
	Linden DeBoer (b) (4)	06 Aug 2020 17:52:02
	(b) (4)	

**US3032115**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:48:59**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:11:12
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	06 Aug 2020 17:52:02

**US3032115**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:48:59**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:11:12
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	06 Aug 2020 17:52:02

US3032115

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:48:59

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:11:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered '06 Aug 2020'	(b) (4) Linden DeBoer (b) (4) (b) (4)	06 Aug 2020 17:52:16

**US3032115**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:48:59**

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered 'Aug 2020'	System	06 Aug 2020 17:52:16

**US3032115**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:48:59**

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered '2020'	System	06 Aug 2020 17:52:16



US3032115

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:48:59

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:11:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered 'Amendment 1 (1)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	06 Aug 2020 17:52:16

US3032115

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:48:59

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:11:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	06 Aug 2020 17:52:16

**US3032115**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:48:59**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:11:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered empty.	(b) (4)	
	Linden DeBoer (b) (4)	06 Aug 2020 17:52:16
	(b) (4)	

**US3032115**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:48:59**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:11:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered empty.	(b) (4) Linden DeBoer (b) (4) (b) (4)	06 Aug 2020 17:52:16

US3032115

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:48:59

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:11:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered 'No (N)'	(b) (4)	
	Linden DeBoer (b) (4)	06 Aug 2020 17:52:16
	(b) (4)	

US3032115

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:48:59

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:11:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 16:25:47

**US3032115**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:48:59**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered 'I'	System	06 Aug 2020 17:52:19

US3032115

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 14:48:59

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:11:43
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	06 Aug 2020 17:52:19



**US3032115**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 09 Jun 2021 14:48:59**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:11:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:52:57

US3032115

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:48:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Myocardial infarction, LLT: Myocardial infarction - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	06 Aug 2020 20:54:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 20:54:59
Data point term sent to Coder	System	06 Aug 2020 20:54:14
User entered 'myocardial infraction'	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:53:40

**US3032115**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:48:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'un UNK 2013'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:53:40

**US3032115**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:48:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:53:40

**US3032115**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:48:59**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:53:40

**US3032115**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:48:59**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
Signature has been broken.	(b) (4)	16 Mar 2021 22:22:06
DataPoint Verified.	Kelsey Kelley (b) (4)	16 Mar 2021 22:22:06
	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	06 Aug 2020 20:53:40
	(b) (4)	

US3032115

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:48:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:53:40

**US3032115**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:48:59**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered 'Jan 2013'	System	06 Aug 2020 20:53:40



**US3032115**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:48:59**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered '2013'	System	06 Aug 2020 20:53:40

**US3032115**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:48:59**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered empty.	System	06 Aug 2020 20:53:40

**US3032115**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:48:59**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered empty.	System	06 Aug 2020 20:53:40

US3032115

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:48:59

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Cerebrovascular accident, LLT: Cerebrovascular accident - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	06 Aug 2020 20:56:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 20:56:00
Data point term sent to Coder	System	06 Aug 2020 20:55:15
User entered 'cerebrovascular accident'	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:54:27

**US3032115**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:48:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'un UNK 2013'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:54:27

**US3032115**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:48:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:54:27

**US3032115**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:48:59**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:54:27

**US3032115**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:48:59**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'un UNK 2013'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:54:27



**US3032115**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:48:59**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:54:27

**US3032115**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:48:59**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered 'Jan 2013'	System	06 Aug 2020 20:54:27

**US3032115**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:48:59**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered '2013'	System	06 Aug 2020 20:54:27

**US3032115**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:48:59**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered 'Jan 2013'	System	06 Aug 2020 20:54:27

**US3032115**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:48:59**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered '2013'	System	06 Aug 2020 20:54:27

US3032115

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:48:59

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured as a separate entry on the Med History eCRF. Please verify and update as appropriate.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 10:37:34
' (Site from DM).		
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured as a separate entry on the Med History eCRF. Please verify and update as appropriate.	Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 13:36:24
' answered with 'Patient had hysterectomy due to multiple miscarriages which is an item in med history.' (Site from DM).		
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured as a separate entry on the Med History eCRF. Please verify and update as appropriate.	(b) (4), (b) (6)	30 Aug 2020 08:15:14
' (Site from DM).		
User coded data point as SOC: Surgical and medical procedures, HLG: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	06 Aug 2020 20:56:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	06 Aug 2020 20:56:00
Data point term sent to Coder	System	06 Aug 2020 20:55:19
User entered 'hysterectomy'	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:54:42

**US3032115**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:48:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'un UNK 1984'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:54:42

**US3032115**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:48:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:54:42



**US3032115**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:48:59**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:54:42

**US3032115**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:48:59**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'un UNK 1984'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:54:42

**US3032115**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:48:59**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:54:42

**US3032115**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:48:59**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered 'Jan 1984'	System	06 Aug 2020 20:54:42

**US3032115**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:48:59**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered '1984'	System	06 Aug 2020 20:54:42

**US3032115**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:48:59**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered 'Jan 1984'	System	06 Aug 2020 20:54:42

**US3032115**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:48:59**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered '1984'	System	06 Aug 2020 20:54:42

US3032115

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:48:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.	(b) (4)	17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Allergy to chemicals, LLT: Alcohol allergy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	06 Aug 2020 23:46:11
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 23:46:11
Data point term sent to Coder	System	06 Aug 2020 20:55:19
User entered 'allergy to alcohol, rash'	Kelsey Kelley (b) (4)	06 Aug 2020 20:55:13



**US3032115**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:48:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'un UNK 1983'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:55:13

**US3032115**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:48:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:55:13

**US3032115**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:48:59**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:55:13

**US3032115**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:48:59**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:55:13

**US3032115**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:48:59**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:55:13

US3032115

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:48:59

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered 'Jan 1983'	System	06 Aug 2020 20:55:13

**US3032115**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:48:59**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered '1983'	System	06 Aug 2020 20:55:13

**US3032115**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:48:59**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered empty.	System	06 Aug 2020 20:55:13



**US3032115**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:48:59**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered empty.	System	06 Aug 2020 20:55:13

US3032115

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:48:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	06 Aug 2020 20:58:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 20:58:04
Data point term sent to Coder	System	06 Aug 2020 20:56:22
User entered 'postmenopausal'	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:55:27

**US3032115**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:48:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'un UNK 1984'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:55:27

**US3032115**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:48:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:55:27

**US3032115**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:48:59**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:55:27

**US3032115**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:48:59**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:55:27

**US3032115**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:48:59**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:55:27

**US3032115**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:48:59**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered 'Jan 1984'	System	06 Aug 2020 20:55:27



**US3032115**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:48:59**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered '1984'	System	06 Aug 2020 20:55:27

**US3032115**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:48:59**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered empty.	System	06 Aug 2020 20:55:27

**US3032115**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:48:59**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered empty.	System	06 Aug 2020 20:55:27

US3032115

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:48:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Spinal fractures and dislocations, PT: Fractured coccyx, LLT: Fractured coccyx - version MedDRA\23.0.	(b) (4) (b) (4) Coder Import (b) (4)	07 Aug 2020 18:00:16
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	07 Aug 2020 18:00:16
Data point term sent to Coder	System	06 Aug 2020 20:56:22
User entered 'broken tailbone'	Kelsey Kelley (b) (4)	06 Aug 2020 20:56:01

US3032115

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:48:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered '05 Aug 2019' reason for change: Data Entry Error	(b) (4)	
	Kelsey Kelley (b) (4)	06 Aug 2020 20:57:18
User entered 'un Aug 2019'	(b) (4)	
	Kelsey Kelley (b) (4)	06 Aug 2020 20:56:01
	(b) (4)	

**US3032115**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 14:48:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:56:01

**US3032115**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 14:48:59**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:56:01

**US3032115**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 14:48:59**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered '05 Aug 2019' reason for change: Data Entry Error	(b) (4)	
	Kelsey Kelley (b) (4)	06 Aug 2020 20:57:18
User entered 'un Aug 2019'	(b) (4)	
	Kelsey Kelley (b) (4)	06 Aug 2020 20:56:01
	(b) (4)	



**US3032115**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 14:48:59**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:56:01

**US3032115**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 14:48:59**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered 'Aug 2019'	System	06 Aug 2020 20:56:01

**US3032115**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 14:48:59**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered '2019'	System	06 Aug 2020 20:56:01

**US3032115**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 14:48:59**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered 'Aug 2019'	System	06 Aug 2020 20:56:01

**US3032115**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 14:48:59**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered '2019'	System	06 Aug 2020 20:56:01

US3032115

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:48:59

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.	(b) (4)	17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
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: Back pain, LLT: Low back pain - version MedDRA\\23.0.	(b) (4) (b) (4) Coder Import (b) (4)	07 Aug 2020 00:36:08
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 00:36:08
Data point term sent to Coder	System	06 Aug 2020 20:57:23
User entered 'back pain-lower lumbar'	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:56:58

**US3032115**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 14:48:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered '05 Aug 2019'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:56:58

**US3032115**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 14:48:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:56:58



US3032115

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:48:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		07 Apr 2021 19:59:12
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:23
DataPoint Un-verified.	(b) (4)	
	Kelsey Kelley (b) (4)	22 Dec 2020 21:58:19
Signature has been broken.	(b) (4)	
	Kelsey Kelley (b) (4)	22 Dec 2020 21:58:19
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Kelsey Kelley (b) (4)	22 Dec 2020 21:58:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	06 Aug 2020 20:56:58
	(b) (4)	

US3032115

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:48:59

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		07 Apr 2021 19:59:12
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:23
DataPoint Un-verified.	(b) (4)	
	Kelsey Kelley (b) (4)	22 Dec 2020 21:58:19
Signature has been broken.	(b) (4)	
	Kelsey Kelley (b) (4)	22 Dec 2020 21:58:19
User entered empty; reason for change Data Entry Error	(b) (4)	
	Kelsey Kelley (b) (4)	22 Dec 2020 21:58:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
	(b) (4)	
User entered '05 Aug 2019'	Kelsey Kelley (b) (4)	06 Aug 2020 20:56:58
	(b) (4)	

**US3032115**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 14:48:59**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:56:58

US3032115

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:48:59

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered 'Aug 2019'	System	06 Aug 2020 20:56:58

**US3032115**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 14:48:59**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered '2019'	System	06 Aug 2020 20:56:58

**US3032115**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 14:48:59**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered empty.	System	22 Dec 2020 21:58:19
User entered 'Aug 2019'	System	06 Aug 2020 20:56:58

**US3032115**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 14:48:59**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered empty.	System	22 Dec 2020 21:58:19
User entered '2019'	System	06 Aug 2020 20:56:58

US3032115

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:48:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Spinal fractures and dislocations, PT: Lumbar vertebral fracture, LLT: Lumbar vertebral fracture - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	(b) (4) 30 Sep 2020 13:28:09
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	(b) (4) 30 Sep 2020 13:28:09
User closed query 'Per DM CLR: Please review and reflect the specific level of the spine affected. Update eCRF as appropriate.	(b) (4), (b) (6)	30 Sep 2020 06:46:42
' (Site from DM).		
Data point term sent to Coder	System	29 Sep 2020 21:45:28
Query 'Per DM CLR: Please review and reflect the specific level of the spine affected. Update eCRF as appropriate.	Samantha Wieseler (b) (4)	29 Sep 2020 21:44:45
' answered with 'updated' (Site from DM).	(b) (4)	
Coding entries removed.	Samantha Wieseler (b) (4)	29 Sep 2020 21:44:41
User entered 'FRACTURED VERTEBRAE-Lumbar' reason for change: Data Entry Error	(b) (4) Samantha Wieseler (b) (4)	(b) (4) 29 Sep 2020 21:44:41
User opened query 'Per DM CLR: Please review and reflect the specific level of the spine affected. Update eCRF as appropriate.	(b) (4), (b) (6)	30 Aug 2020 08:15:02
' (Site from DM).		
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Spinal fractures and dislocations, PT: Spinal fracture, LLT: Fractured vertebra - version MedDRA\23.0.	Coder Import (b) (4)	(b) (4) 07 Aug 2020 22:14:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	(b) (4) 07 Aug 2020 22:14:39
Data point term sent to Coder	System	06 Aug 2020 20:58:25
User entered 'fractured vertebrae'	Kelsey Kelley (b) (4)	06 Aug 2020 20:57:49
	(b) (4)	



US3032115

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:48:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered '05 Aug 2019'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:57:49

**US3032115**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 14:48:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:57:49

**US3032115**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 14:48:59**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:57:49

**US3032115**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 14:48:59**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered '05 Aug 2019'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:57:49

**US3032115**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 14:48:59**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:57:49

US3032115

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:48:59

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered 'Aug 2019'	System	06 Aug 2020 20:57:49

**US3032115**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 14:48:59**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered '2019'	System	06 Aug 2020 20:57:49

US3032115

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:48:59

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered 'Aug 2019'	System	06 Aug 2020 20:57:49



**US3032115**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 14:48:59**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered '2019'	System	06 Aug 2020 20:57:49

US3032115

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:48:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	06 Aug 2020 21:00:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 21:00:05
Data point term sent to Coder	System	06 Aug 2020 20:58:25
User entered 'hypertension'	Kelsey Kelley (b) (4)	06 Aug 2020 20:58:10

**US3032115**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 14:48:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'un UNK 2013'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:58:10

**US3032115**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 14:48:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:58:10

**US3032115**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 14:48:59**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:58:10

**US3032115**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 14:48:59**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:58:10

**US3032115**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 14:48:59**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:58:10

**US3032115**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 14:48:59**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered 'Jan 2013'	System	06 Aug 2020 20:58:10



**US3032115**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 14:48:59**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered '2013'	System	06 Aug 2020 20:58:10

**US3032115**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 14:48:59**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered empty.	System	06 Aug 2020 20:58:10

**US3032115**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 14:48:59**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered empty.	System	06 Aug 2020 20:58:10

US3032115

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:48:59

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.	(b) (4)	17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	06 Aug 2020 21:00:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 21:00:05
Data point term sent to Coder	System	06 Aug 2020 20:58:27
User entered 'anxiety'	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:58:25

**US3032115**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 14:48:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'un UNK 2010'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:58:25

**US3032115**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 14:48:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:58:25

**US3032115**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 14:48:59**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:58:25

**US3032115**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 14:48:59**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:58:25



**US3032115**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 14:48:59**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:58:25

**US3032115**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 14:48:59**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered 'Jan 2010'	System	06 Aug 2020 20:58:25

**US3032115**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 14:48:59**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered '2010'	System	06 Aug 2020 20:58:25

**US3032115**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 14:48:59**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered empty.	System	06 Aug 2020 20:58:25

**US3032115**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 14:48:59**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered empty.	System	06 Aug 2020 20:58:25

US3032115

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:48:59

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:24
User coded data point as SOC: Gastrointestinal disorders, HLGIT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Acid reflux (esophageal) - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	18 Nov 2020 17:15:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Nov 2020 17:15:46
Data point term sent to Coder	System	18 Nov 2020 17:15:12
Coding entries removed.	Linden DeBoer (b) (4)	18 Nov 2020 17:14:22
Signature has been broken.	(b) (4) Linden DeBoer (b) (4)	18 Nov 2020 17:14:22
User entered 'acid reflux' reason for change: Data Entry Error	(b) (4) Linden DeBoer (b) (4)	18 Nov 2020 17:14:22
User signature succeeded.	(b) (4) Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User coded data point as SOC: Gastrointestinal disorders, HLGIT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Aug 2020 21:00:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 21:00:48
Data point term sent to Coder	System	06 Aug 2020 20:59:28
User entered 'gastroesophageal reflux disease'	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:58:56

**US3032115**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 14:48:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'un UNK 2010'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:58:56

**US3032115**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 14:48:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:58:56



**US3032115**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 14:48:59**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:58:56

**US3032115**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 14:48:59**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:58:56

**US3032115**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 14:48:59**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:58:56

**US3032115**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 14:48:59**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered 'Jan 2010'	System	06 Aug 2020 20:58:56

**US3032115**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 14:48:59**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered '2010'	System	06 Aug 2020 20:58:56

**US3032115**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 14:48:59**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered empty.	System	06 Aug 2020 20:58:56

**US3032115**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 14:48:59**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered empty.	System	06 Aug 2020 20:58:56

US3032115

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 14:48:59

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.	(b) (4)	17 Dec 2020 20:13:49
User coded data point as SOC: Pregnancy, puerperium and perinatal conditions, HLGTT: Abortions and stillbirth, HLT: Abortions spontaneous, PT: Abortion spontaneous, LLT: Miscarriage - version MedDRA\23.0.	Coder Import (b) (4)	18 Nov 2020 13:22:05
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	18 Nov 2020 13:22:05
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User closed query 'Per DM CLR: Please review and ensure that each Miscarriage events were recorded separately. Update eCRF as appropriate. '(Site from DM).	(b) (4) (b) (4), (b) (6)	16 Sep 2020 10:38:20
Query 'Per DM CLR: Please review and ensure that each Miscarriage events were recorded separately. Update eCRF as appropriate. ' answered with 'data updated to better describe event; recurred several times' (Site from DM).	Kelsey Kelley (b) (4)	15 Sep 2020 13:35:18
Data point term sent to Coder	System	15 Sep 2020 13:34:44
Coding entries removed.	Kelsey Kelley (b) (4)	15 Sep 2020 13:34:42
User entered 'recurring MISCARRIAGES' reason for change: Data Entry Error	(b) (4)	
	Kelsey Kelley (b) (4)	15 Sep 2020 13:34:42
User opened query 'Per DM CLR: Please review and ensure that each Miscarriage events were recorded separately. Update eCRF as appropriate. '(Site from DM).	(b) (4), (b) (6)	30 Aug 2020 08:15:29
User coded data point as SOC: Pregnancy, puerperium and perinatal conditions, HLGTT: Abortions and stillbirth, HLT: Abortions spontaneous, PT: Abortion spontaneous, LLT: Miscarriage - version MedDRA\23.0.	Coder Import (b) (4)	17 Aug 2020 07:27:23
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	17 Aug 2020 07:27:23
Data point term sent to Coder	System	06 Aug 2020 21:00:32
User entered 'multiple miscarriages'	Kelsey Kelley (b) (4)	06 Aug 2020 20:59:38



**US3032115**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 14:48:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'un UNK 1984'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:59:38

**US3032115**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 14:48:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:59:38

**US3032115**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 14:48:59**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:59:38

**US3032115**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 14:48:59**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'un UNK 1984'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:59:38

**US3032115**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 14:48:59**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:59:38

**US3032115**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 14:48:59**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered 'Jan 1984'	System	06 Aug 2020 20:59:38

**US3032115**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 14:48:59**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered '1984'	System	06 Aug 2020 20:59:38

**US3032115**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 14:48:59**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered 'Jan 1984'	System	06 Aug 2020 20:59:38



**US3032115**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 14:48:59**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered '1984'	System	06 Aug 2020 20:59:38

US3032115

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 14:48:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User coded data point as SOC: Vascular disorders, HLT: Aneurysms and artery dissections, HLT: Aortic aneurysms and dissections, PT: Aortic aneurysm, LLT: Aortic aneurysm - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	06 Aug 2020 21:02:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 21:02:04
Data point term sent to Coder	System	06 Aug 2020 21:00:32
User entered 'aortic aneurysm'	Kelsey Kelley (b) (4)	06 Aug 2020 21:00:06

**US3032115**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 14:48:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'un UNK 2013'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 21:00:06

**US3032115**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 14:48:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 21:00:06

**US3032115**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 14:48:59**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 21:00:06

**US3032115**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 14:48:59**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'un UNK 2013'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 21:00:06

**US3032115**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 14:48:59**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 21:00:06

**US3032115**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 14:48:59**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered 'Jan 2013'	System	06 Aug 2020 21:00:06



**US3032115**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 14:48:59**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered '2013'	System	06 Aug 2020 21:00:06

**US3032115**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 14:48:59**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered 'Jan 2013'	System	06 Aug 2020 21:00:06

**US3032115**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 14:48:59**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered '2013'	System	06 Aug 2020 21:00:06

US3032115

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 14:48:59

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	29 Sep 2020 21:44:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 21:44:42
Data point term sent to Coder	System	29 Sep 2020 21:44:27
User entered 'Hypercholesterolemia'	Samantha Wieseler (b) (4) (b) (4)	29 Sep 2020 21:44:03

**US3032115**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 14:48:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'UN UNK 2012'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	29 Sep 2020 21:44:03

US3032115

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 14:48:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered '0'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	29 Sep 2020 21:44:03

**US3032115**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 14:48:59**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	29 Sep 2020 21:44:03

**US3032115**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 14:48:59**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered empty.	(b) (4) Samantha Wieseler (b) (4) (b) (4)	29 Sep 2020 21:44:03



**US3032115**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 14:48:59**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:13:49
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered '0'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	29 Sep 2020 21:44:03

**US3032115**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 14:48:59**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered 'Jan 2012'	System	29 Sep 2020 21:44:03

**US3032115**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 14:48:59**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered '2012'	System	29 Sep 2020 21:44:03

**US3032115**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 14:48:59**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered empty.	System	29 Sep 2020 21:44:03

**US3032115**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 14:48:59**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered empty.	System	29 Sep 2020 21:44:03

US3032115

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 14:48:59

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		07 Apr 2021 19:59:38
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).		01 Apr 2021 01:34:46
Query 'Per DM CLR: Please note that there is no Con Samantha Wieseler Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'no conmed taken for this ' (Site from DM).	(b) (4) (b) (4)	29 Mar 2021 14:00:53
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 05:14:23
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Paroxysmal atrial fibrillation - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	(b) (4) 16 Mar 2021 22:08:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	(b) (4) 16 Mar 2021 22:08:00
Data point term sent to Coder	System	16 Mar 2021 22:07:20
User entered 'Paroxysmal atrial Fibrillation'	Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 22:06:56

**US3032115**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 14:48:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		07 Apr 2021 19:59:38
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'un UNK 2007'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 22:06:56

**US3032115**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 14:48:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		07 Apr 2021 19:59:38
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 22:06:56



**US3032115**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 14:48:59**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		07 Apr 2021 19:59:38
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 22:06:56

**US3032115**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 14:48:59**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		07 Apr 2021 19:59:38
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 22:06:56

**US3032115**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 14:48:59**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		07 Apr 2021 19:59:38
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 22:06:56

**US3032115**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 14:48:59**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered 'Jan 2007'	System	16 Mar 2021 22:06:56

**US3032115**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 14:48:59**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered '2007'	System	16 Mar 2021 22:06:56

**US3032115**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 14:48:59**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered empty.	System	16 Mar 2021 22:06:56

**US3032115**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 14:48:59**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered empty.	System	16 Mar 2021 22:06:56

US3032115

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 14:48:59

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		07 Apr 2021 19:59:48
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).		01 Apr 2021 01:35:01
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'subjects asthma is not bad enough for a medication to be prescribed.' (Site from DM).	Samantha Wieseler (b) (4)	29 Mar 2021 14:01:47
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4)	
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 05:15:05
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	16 Mar 2021 22:09:57
Data point term sent to Coder	(b) (4)	
User entered 'asthma'	Coder Import (b) (4)	16 Mar 2021 22:09:57
	(b) (4)	
	System	16 Mar 2021 22:08:28
	Kelsey Kelley (b) (4)	16 Mar 2021 22:07:45
	(b) (4)	



**US3032115**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 14:48:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		07 Apr 2021 19:59:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'un UNK 1965'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 22:07:45

**US3032115**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 14:48:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		07 Apr 2021 19:59:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 22:07:45

**US3032115**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 14:48:59**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		07 Apr 2021 19:59:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 22:07:45

**US3032115**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 14:48:59**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		07 Apr 2021 19:59:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 22:07:45

**US3032115**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 14:48:59**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		07 Apr 2021 19:59:48
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 22:07:45

**US3032115**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 14:48:59**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered 'Jan 1965'	System	16 Mar 2021 22:07:45

**US3032115**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 14:48:59**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered '1965'	System	16 Mar 2021 22:07:45

**US3032115**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 14:48:59**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered empty.	System	16 Mar 2021 22:07:45



**US3032115**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 14:48:59**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered empty.	System	16 Mar 2021 22:07:45

US3032115

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 14:48:59

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		07 Apr 2021 20:00:00
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Pulmonary vascular disorders, HLT: Pulmonary thrombotic and embolic conditions, PT: Pulmonary embolism, LLT: Pulmonary embolism - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	17 Mar 2021 12:00:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	17 Mar 2021 12:00:50
Data point term sent to Coder	System	16 Mar 2021 22:08:47
User entered 'pulmonary embolism of left lung'	Kelsey Kelley (b) (4)	16 Mar 2021 22:08:33

**US3032115**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 14:48:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		07 Apr 2021 20:00:00
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'un UNK 2008'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 22:08:33

**US3032115**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 14:48:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		07 Apr 2021 20:00:00
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 22:08:33

**US3032115**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 14:48:59**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		07 Apr 2021 20:00:00
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 22:08:33

**US3032115**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 14:48:59**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		07 Apr 2021 20:00:00
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 22:08:33

**US3032115**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 14:48:59**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		07 Apr 2021 20:00:00
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 22:08:33

**US3032115**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 14:48:59**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered 'Jan 2008'	System	16 Mar 2021 22:08:33



**US3032115**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 14:48:59**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered '2008'	System	16 Mar 2021 22:08:33

**US3032115**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 14:48:59**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered empty.	System	16 Mar 2021 22:08:33

**US3032115**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 14:48:59**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered empty.	System	16 Mar 2021 22:08:33

US3032115

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 14:48:59

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		07 Apr 2021 20:00:10
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User coded data point as SOC: Psychiatric disorders, HLTG: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Mar 2021 22:11:03
Data point term sent to Coder	(b) (4)	
User entered 'insomnia'	Coder Import (b) (4)	16 Mar 2021 22:11:03
	(b) (4)	
	System	16 Mar 2021 22:09:48
	Kelsey Kelley (b) (4)	16 Mar 2021 22:08:47
	(b) (4)	

**US3032115**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 14:48:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		07 Apr 2021 20:00:10
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'un UNK 2006'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 22:08:47

**US3032115**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 14:48:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		07 Apr 2021 20:00:10
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 22:08:47

**US3032115**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 14:48:59**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		07 Apr 2021 20:00:10
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 22:08:47

**US3032115**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 14:48:59**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		07 Apr 2021 20:00:10
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 22:08:47



**US3032115**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 14:48:59**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		07 Apr 2021 20:00:10
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 22:08:47

**US3032115**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 14:48:59**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered 'Jan 2006'	System	16 Mar 2021 22:08:47

**US3032115**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 14:48:59**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered '2006'	System	16 Mar 2021 22:08:47

**US3032115**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 14:48:59**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered empty.	System	16 Mar 2021 22:08:47

**US3032115**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 14:48:59**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered empty.	System	16 Mar 2021 22:08:47

US3032115

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 14:48:59

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		07 Apr 2021 20:00:27
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:21
User closed query 'Per DM CLR: Please verify the type of the Neuropathy (i.e. sensory or motor). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 01:35:18
' (Site from DM).		
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Peripheral sensory neuropathy, LLT: Sensory peripheral neuropathy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Mar 2021 14:18:22
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Mar 2021 14:18:22
Query 'Per DM CLR: Please verify the type of the Neuropathy (i.e. sensory or motor). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	Samantha Wieseler (b) (4) (b) (4)	29 Mar 2021 14:02:54
' answered with 'updated' (Site from DM).		
Data point term sent to Coder	System	29 Mar 2021 14:02:40
Signature has been broken.	Samantha Wieseler (b) (4) (b) (4)	29 Mar 2021 14:02:37
User entered 'sensory NEUROPATHY OF RIGHT ARM, NECK, AND HAND' reason for change: Data Entry Error	Samantha Wieseler (b) (4) (b) (4)	29 Mar 2021 14:02:37
User opened query 'Per DM CLR: Please verify the type of the Neuropathy (i.e. sensory or motor). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4), (b) (6)	29 Mar 2021 05:15:35
' (Site from DM).		
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	18 Mar 2021 21:11:10
Data point term sent to Coder	System	16 Mar 2021 22:09:47

US3032115

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 14:48:59

[Condition](#)

Audit	User	Time (GMT)
User entered 'neuropathy of right arm, neck, and hand'	Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 22:09:37

**US3032115**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 14:48:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		07 Apr 2021 20:00:27
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'un UNK 2019'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 22:09:37



**US3032115**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 14:48:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		07 Apr 2021 20:00:27
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 22:09:37

**US3032115**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 14:48:59**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		07 Apr 2021 20:00:27
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 22:09:37

**US3032115**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 14:48:59**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		07 Apr 2021 20:00:27
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 22:09:37

**US3032115**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 14:48:59**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		07 Apr 2021 20:00:27
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 22:09:37

US3032115

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 14:48:59

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered 'Jan 2019'	System	16 Mar 2021 22:09:37

**US3032115**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 14:48:59**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered '2019'	System	16 Mar 2021 22:09:37

**US3032115**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 14:48:59**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered empty.	System	16 Mar 2021 22:09:37

**US3032115**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 14:48:59**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered empty.	System	16 Mar 2021 22:09:37



US3032115

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 14:48:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		07 Apr 2021 20:00:32
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Visual impairment and blindness (excl colour blindness), PT: Visual impairment, LLT: Visual impairment - version MedDRA\\23.0.	(b) (4) (b) (4) Coder Import (b) (4)	17 Mar 2021 11:54:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	17 Mar 2021 11:54:41
Data point term sent to Coder	System	16 Mar 2021 22:14:52
User entered 'vision changes'	Kelsey Kelley (b) (4)	16 Mar 2021 22:14:39

**US3032115**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 09 Jun 2021 14:48:59**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		07 Apr 2021 20:00:32
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'un UNK 2013'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 22:14:39

**US3032115**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 09 Jun 2021 14:48:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		07 Apr 2021 20:00:32
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 22:14:39

**US3032115**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 09 Jun 2021 14:48:59**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		07 Apr 2021 20:00:32
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 22:14:39

**US3032115**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 09 Jun 2021 14:48:59**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		07 Apr 2021 20:00:32
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 22:14:39

**US3032115**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 09 Jun 2021 14:48:59**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		07 Apr 2021 20:00:32
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 22:14:39

**US3032115**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 09 Jun 2021 14:48:59**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered 'Jan 2013'	System	16 Mar 2021 22:14:39

**US3032115**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 09 Jun 2021 14:48:59**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered '2013'	System	16 Mar 2021 22:14:39



US3032115

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 14:48:59

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered empty.	System	16 Mar 2021 22:14:39

**US3032115**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 09 Jun 2021 14:48:59**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered empty.	System	16 Mar 2021 22:14:39

US3032115

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:14:14
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:49:00

US3032115

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:59

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:14:14
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	06 Aug 2020 20:49:11
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	06 Aug 2020 20:49:11
User closed query 'The Assessment Date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	06 Aug 2020 20:49:11
User entered '6 Aug 2020' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	06 Aug 2020 20:49:11
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	06 Aug 2020 20:49:00
User opened query 'The Assessment Date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	06 Aug 2020 20:49:00
User entered '5 Aug 2020'	Kelsey Kelley (b) (4)	06 Aug 2020 20:49:00

**US3032115**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:48:59**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:14:14
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered '11:15'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:49:00

**US3032115**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:48:59**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered '6 Aug 2020 11:15'	System	06 Aug 2020 20:49:11
User entered '5 Aug 2020 11:15'	System	06 Aug 2020 20:49:00

US3032115

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:59

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:14:14
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered '154.9' cm	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 20:49:00
DataPoint set to visible.	(b) (4) System	06 Aug 2020 17:52:19

US3032115

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:59

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:14:14
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered '72.1' kg	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 20:49:00
DataPoint set to visible.	(b) (4) System	06 Aug 2020 17:52:19



US3032115

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:59

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
Amendment Manager: User entered '30.04917'	System	16 Sep 2020 23:45:41
User entered '30.0'	System	06 Aug 2020 20:49:00
DataPoint set to visible.	System	06 Aug 2020 17:52:19

**US3032115**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:48:59**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered 'kg/m2'	System	06 Aug 2020 20:49:00
DataPoint set to visible.	System	06 Aug 2020 17:52:19

US3032115

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:14:14
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:22:03
User closed query 'Per CDM RQ: Please remove the unit of temperature.	(b) (4)	
Thanks ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 05:59:29
Query 'Per CDM RQ: Please remove the unit of temperature.		
Thanks ' answered with 'data updated' (Site from DM).	Linden DeBoer (b) (4)	07 Oct 2020 13:42:10
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	
User opened query 'Per CDM RQ: Please remove the unit of temperature.	(b) (4), (b) (6)	07 Oct 2020 05:17:06
Thanks ' (Site from DM).		
User closed query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE on this page and the unit should not remain (ND for “Not done” and not left empty). Please update accordingly.	(b) (4), (b) (6)	07 Oct 2020 05:17:06
' (Site from DM).		
Query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE on this page and the unit should not remain (ND for “Not done” and not left empty). Please update accordingly.	Linden DeBoer (b) (4)	06 Oct 2020 15:44:59
' answered with 'Data updated :Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE on this page (ND for “Not done” and not left empty). Please note that the unit should not remain. Please update accordingly. ' (Site from DM).	(b) (4)	
Signature has been broken.	Linden DeBoer (b) (4)	06 Oct 2020 15:44:54
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	
	Linden DeBoer (b) (4)	06 Oct 2020 15:44:54
	(b) (4)	

US3032115

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:59

Temperature (xxx.x)

Audit	User	Time (GMT)
User opened query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE on this page and the unit should not remain (ND for "Not done" and not left empty). Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 14:16:17
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered '36.7' C	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 20:49:00
	(b) (4)	

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:14:14
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User closed query 'Per CDM: Please note that the temperature is marked as "ND" and the Route of measurement is not required. Review and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Dec 2020 06:43:46
Query 'Per CDM: Please note that the temperature is marked as "ND" and the Route of measurement is not required. Review and update as appropriate. ' answered with 'Updated' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	14 Dec 2020 15:54:26
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	14 Dec 2020 15:54:22
User entered empty; reason for change Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	14 Dec 2020 15:54:22
User opened query 'Per CDM: Please note that the temperature is marked as "ND" and the Route of measurement is not required. Review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 10:59:09
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 16:59:27
User entered 'Oral (Oral)'	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:49:00

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:14:14
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:49:00

US3032115

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:14:14
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:22:03
User closed query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Oct 2020 05:17:08
Query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please update accordingly.' answered with 'Data updated :Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE on this page (ND for "Not done" and not left empty). Please note that the unit should not remain. Please update accordingly. ' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	06 Oct 2020 15:45:07
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	06 Oct 2020 15:44:54
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4) (b) (4)	06 Oct 2020 15:44:54
User opened query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 14:16:07
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 16:59:27
User entered '75'	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:49:00

**US3032115**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:48:59**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered 'bpm'	System	06 Aug 2020 20:49:00



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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:14:14
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:22:03
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	06 Oct 2020 15:44:54
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4)	06 Oct 2020 15:44:54
User signature succeeded.	(b) (4)	
	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
	(b) (4)	
User entered '16'	Kelsey Kelley (b) (4)	06 Aug 2020 20:49:00
	(b) (4)	

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered 'breaths/min'	System	06 Aug 2020 20:49:00

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:59

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:14:14
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:22:03
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	06 Oct 2020 15:44:54
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4)	06 Oct 2020 15:44:54
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
	(b) (4)	
User entered '146'	Kelsey Kelley (b) (4)	06 Aug 2020 20:49:00
	(b) (4)	

**US3032115**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:48:59**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered 'mmHg'	System	06 Aug 2020 20:49:00

US3032115

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:14:14
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:22:03
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	06 Oct 2020 15:44:54
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4)	06 Oct 2020 15:44:54
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
	(b) (4)	
User entered '88'	Kelsey Kelley (b) (4)	06 Aug 2020 20:49:00
	(b) (4)	

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered 'mmHg'	System	06 Aug 2020 20:49:00

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:59

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:59

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03



US3032115

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:48:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:14:21
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:49:17

US3032115

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:48:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:14:21
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
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)	07 Sep 2020 10:42:32
User opened query 'The Physical Examination Date isSystem prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		03 Sep 2020 15:33:28
User entered '6 Aug 2020'	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:49:17

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:48:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:15:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered '6 Aug 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:43:32

US3032115

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:48:59

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:15:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:43:32

US3032115

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:48:59

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:15:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User closed query 'Is the participant of childbearing potential is No, however reason is missing. Please provide.' (Site from System).	(b) (4) System	06 Aug 2020 20:47:06
User entered 'Surgically sterile (SURGICALLY STERILE)' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	06 Aug 2020 20:47:06
User opened query 'Is the participant of childbearing potential is No, however reason is missing. Please provide.' (Site from System).	(b) (4) System	06 Aug 2020 20:43:32
User entered empty.	Kelsey Kelley (b) (4)	06 Aug 2020 20:43:32

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:48:59

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:15:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:43:32

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:48:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:15:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User closed query 'Surgically sterile been entered, however date of surgery is missing. Please provide.' (Site from System).	(b) (4) System	06 Aug 2020 20:49:26
User entered 'un UNK 1984' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:49:26
User opened query 'Surgically sterile been entered, however date of surgery is missing. Please provide.' (Site from System).	System	06 Aug 2020 20:47:06
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:43:32

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Folder: Screening

Form: Childbearing Potential

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Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:15:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:43:32



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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:48:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:15:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:43:32

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Folder: Screening

Form: Childbearing Potential

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[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:15:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:43:32

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:48:59

**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 02:13:03
DataPoint Verified.		17 Dec 2020 20:15:06
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:40:49

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Folder: Screening

Form: Risk of Exposure

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**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 02:13:03
DataPoint Verified.		17 Dec 2020 20:15:06
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:40:49

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Folder: Screening

Form: Risk of Exposure

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**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 02:13:03
DataPoint Verified.		17 Dec 2020 20:15:06
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:40:49

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Folder: Screening

Form: Risk of Exposure

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**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 02:13:03
DataPoint Verified.		17 Dec 2020 20:15:06
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:40:49

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Folder: Screening

Form: Risk of Exposure

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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 02:13:03
DataPoint Verified.		17 Dec 2020 20:15:06
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:40:49

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Folder: Screening

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[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:15:06
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:40:49



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Folder: Screening

Form: Risk of Exposure

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**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 02:13:03
DataPoint Verified.		17 Dec 2020 20:15:06
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:40:49

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Folder: Screening

Form: Risk of Exposure

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**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:15:06
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:40:49

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Folder: Screening

Form: Risk of Exposure

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[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 02:13:03
DataPoint Verified.		17 Dec 2020 20:15:06
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:40:49

US3032115

Folder: Screening

Form: Risk of Exposure

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**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 02:13:03
DataPoint Verified.		17 Dec 2020 20:15:06
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:40:49

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Folder: Screening

Form: Risk of Exposure

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**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:15:06
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:40:49

US3032115

Folder: Screening

Form: Risk of Exposure

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[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:15:06
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:40:49

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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:15:06
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:40:49

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Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 20:40:49
	(b) (4)	



US3032115

Folder: Screening

Form: Risk of Exposure

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[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:15:06
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:40:49

US3032115

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:48:59

**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 02:13:03
DataPoint Verified.		17 Dec 2020 20:15:06
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:40:49

US3032115

Folder: Screening

Form: Risk of Exposure

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**Resides in high density housing** (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:15:06
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:40:49

US3032115

Folder: Screening

Form: Risk of Exposure

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**Resides in low density, multi-family setting without** (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:15:06
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:40:49

US3032115

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:48:59

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:15:06
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered 'l'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:40:49

US3032115

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:48:59

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 20:40:49

US3032115

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:48:59

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		17 Dec 2020 20:15:06
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:40:49

US3032115

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:48:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:15:10
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	06 Aug 2020 17:52:45



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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:48:59

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:15:10
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered '06 Aug 2020'	(b) (4) Linden DeBoer (b) (4) (b) (4)	06 Aug 2020 17:52:45

US3032115

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:48:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:15:10
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered 'Clinic (Clinic)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	06 Aug 2020 17:52:45

**US3032115**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:48:59**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
User entered 'VISIT1'	System	06 Aug 2020 17:52:45

US3032115

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:48:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 20:15:17
User entered '06 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 17:04:18

US3032115

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:48:59

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 20:15:17
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 02:33:45
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:33:45
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	06 Aug 2020 17:04:18
User entered '101479' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 17:04:18

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:48:59

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 20:15:17
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 17:04:18

US3032115

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:48:59

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)	24 Apr 2021 14:00:19
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 20:15:17
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	25 Aug 2020 18:53:04

US3032115

Folder: Visit 1 Day 1

Form: Randomization

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Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:21
User closed query 'Significant cardiac disease is recorded as Yes, but Cohort group is not recorded as 'at risk'. Please review and reconcile.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Mar 2021 11:58:32
Query 'Significant cardiac disease is recorded as Yes, but Cohort group is not recorded as 'at risk'. Please review and reconcile.' answered with 'DCF was submitted as subject has a significant cardiac disease and should have been stratified into the "at risk" group.' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	26 Mar 2021 13:37:25
User opened query 'Significant cardiac disease is recorded as Yes, but Cohort group is not recorded as 'at risk'. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 14:12:41
Query 'Significant cardiac disease is recorded as Yes but Cohort group is not recorded as 'at risk'. Please review and reconcile.' canceled (Site from System).		25 Mar 2021 14:12:31
DataPoint Verified.		17 Dec 2020 20:15:17
User opened query 'Significant cardiac disease is recorded as Yes, but Cohort group is not recorded as 'at risk'. Please review and reconcile.' (Site from System).	System	25 Aug 2020 18:54:14
User entered 'Yes (Y)' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	25 Aug 2020 18:54:14
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	25 Aug 2020 18:53:04



US3032115

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:48:59

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 20:15:17
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	25 Aug 2020 18:53:04

**US3032115**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 14:48:59**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 20:15:17
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	25 Aug 2020 18:53:04

US3032115

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:48:59

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 20:15:17
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	25 Aug 2020 18:53:04

US3032115

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:48:59

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:15:26
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:47:13
User closed query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 06:26:09
Query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' answered with 'updated' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	09 Oct 2020 13:45:49
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	09 Oct 2020 13:45:36
User entered missing code ND - Not Done; reason for change Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	09 Oct 2020 13:45:36
User opened query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 12:04:31
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 16:59:27
User entered '154.9' cm	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:52:24

US3032115

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:48:59

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:15:26
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:47:13
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	
Signature has been broken.	Kelsey Kelley (b) (4)	09 Oct 2020 13:45:41
	(b) (4)	09 Oct 2020 13:45:36
User entered missing code ND - Not Done; reason for change Data Entry Error	Kelsey Kelley (b) (4)	09 Oct 2020 13:45:36
User signature succeeded.	(b) (4)	
	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered '154.9' kg	(b) (4)	
	Kelsey Kelley (b) (4)	06 Aug 2020 20:52:24
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:48:59

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:15:26
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:47:13
User closed query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 06:26:09
Query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' answered with 'updated' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	09 Oct 2020 13:45:49
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	09 Oct 2020 13:45:36
User entered missing code ND - Not Done; reason for change Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	09 Oct 2020 13:45:36
User opened query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 12:04:31
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 16:59:27
User entered '154.9' cm	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:52:24

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:48:59

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:15:26
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:47:13
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	
Signature has been broken.	Kelsey Kelley (b) (4)	09 Oct 2020 13:45:41
	(b) (4)	09 Oct 2020 13:45:36
User entered missing code ND - Not Done; reason for change Data Entry Error	Kelsey Kelley (b) (4)	09 Oct 2020 13:45:36
User signature succeeded.	(b) (4)	
	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered '154.9' kg	(b) (4)	
	Kelsey Kelley (b) (4)	06 Aug 2020 20:52:24
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
User accepted default value 'Pre-Dose (PREDOSE)'	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:52:24



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:15:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:52:24

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:15:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered '6 Aug 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:52:24

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:15:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered '11:15'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:52:24

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:59

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
User entered '6 Aug 2020 11:15'	System	06 Aug 2020 20:52:24

US3032115

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:15:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered '36.7' C	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:52:24

US3032115

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:15:26
User signature succeeded.	(b) (4)	28 Sep 2020 16:59:27
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:52:24

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:15:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:52:24

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:15:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered '75'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:52:24



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
User entered 'bpm'	System	06 Aug 2020 20:52:24

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:15:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered '16'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:52:24

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
User entered 'breaths/min'	System	06 Aug 2020 20:52:24

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:15:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered '146'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:52:24

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
User entered 'mmHg'	System	06 Aug 2020 20:52:24

US3032115

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:15:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered '88'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:52:24

US3032115

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
User entered 'mmHg'	System	06 Aug 2020 20:52:24

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:48:59

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:15:26
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:47:13
User closed query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 06:26:09
Query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' answered with 'updated' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	09 Oct 2020 13:45:49
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	09 Oct 2020 13:45:36
User entered missing code ND - Not Done; reason for change Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	09 Oct 2020 13:45:36
User opened query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 12:04:31
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 16:59:27
User entered '154.9' cm	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:52:24



US3032115

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:48:59

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:15:26
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:47:13
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	
Signature has been broken.	Kelsey Kelley (b) (4)	09 Oct 2020 13:45:41
	(b) (4)	09 Oct 2020 13:45:36
User entered missing code ND - Not Done; reason for change Data Entry Error	Kelsey Kelley (b) (4)	09 Oct 2020 13:45:36
User signature succeeded.	(b) (4)	
	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered '154.9' kg	(b) (4)	
	Kelsey Kelley (b) (4)	06 Aug 2020 20:52:24
	(b) (4)	

US3032115

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
User accepted default value 'Post-Dose (POSTDOSE)'	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:52:24

US3032115

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:15:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:52:24

US3032115

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:15:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered '6 Aug 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:52:24

US3032115

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:15:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	13 Aug 2020 06:57:25
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with '30 minutes per protocol' (Site from System).	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:52:43
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).		06 Aug 2020 20:52:24
User entered '13:15'	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:52:24

US3032115

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:59

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
User entered '6 Aug 2020 13:15'	System	06 Aug 2020 20:52:24

US3032115

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:15:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered '36.6' C	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:52:24

US3032115

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:15:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:52:24



US3032115

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:15:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:52:24

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:15:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered '63'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:52:24

**US3032115**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:48:59**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
User entered 'bpm'	System	06 Aug 2020 20:52:24

US3032115

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:15:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered '16'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:52:24

US3032115

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
User entered 'breaths/min'	System	06 Aug 2020 20:52:24

US3032115

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:15:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered '132'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:52:24

US3032115

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
User entered 'mmHg'	System	06 Aug 2020 20:52:24

US3032115

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:59

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:15:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered '82'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 20:52:24



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
User entered 'mmHg'	System	06 Aug 2020 20:52:24

US3032115

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:48:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:15:29
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 21:00:32

US3032115

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:48:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:15:29
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered '6 Aug 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 21:00:32

US3032115

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:48:59

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:15:49
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	06 Aug 2020 17:53:24

US3032115

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:48:59

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:15:49
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered empty.	(b) (4)	
	Linden DeBoer (b) (4)	06 Aug 2020 17:53:24
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:48:59

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)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:15:49
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered empty.	(b) (4) Linden DeBoer (b) (4) (b) (4)	06 Aug 2020 17:53:24

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:48:59

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
User entered 'MRNA-1273 OR PLACEBO'	System	06 Aug 2020 17:53:24

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:48:59

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:15:49
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered '06 Aug 2020'	(b) (4) Linden DeBoer (b) (4) (b) (4)	06 Aug 2020 17:53:24



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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:48:59

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:15:49
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered '12:45'	(b) (4) Linden DeBoer (b) (4) (b) (4)	06 Aug 2020 17:53:24

US3032115

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:48:59

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
User entered '06 Aug 2020 12:45'	System	06 Aug 2020 17:53:24

US3032115

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:48:59

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:15:49
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered 'Left Arm (LEFT ARM)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	06 Aug 2020 17:53:24

US3032115

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:48:59

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:15:49
User entered 'ONCE'	System	06 Aug 2020 17:53:24

US3032115

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:48:59

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
User entered 'INTRAMUSCULAR'	System	06 Aug 2020 17:53:24

US3032115

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:48:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:16:10
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 21:01:03

US3032115

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:48:59

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:16:10
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered '6 Aug 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 21:01:03

US3032115

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:48:59

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:16:10
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered '12:07'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 21:01:03



**US3032115**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:48:59**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
User entered '6 Aug 2020 12:07'	System	06 Aug 2020 21:01:03

US3032115

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:48:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:16:21
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered '6 Aug 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 21:01:15

US3032115

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:48:59

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 21:01:15

US3032115

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:48:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:16:21
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 21:01:15

US3032115

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:48:59

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:16:21
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered '11:50'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 21:01:15

**US3032115**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 14:48:59**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
User entered '6 Aug 2020 11:50'	System	06 Aug 2020 21:01:15

US3032115

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:48:59

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 21:01:15

US3032115

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:48:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:16:21
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 21:01:15



US3032115

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:48:59

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:16:21
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 21:01:15

US3032115

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:48:59

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
User entered empty.	System	06 Aug 2020 21:01:15

US3032115

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:48:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:16:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 21:02:28

**US3032115**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:48:59**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
User entered 'I'	System	06 Aug 2020 21:02:28

US3032115

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
Data entry locked.	System	06 Aug 2020 17:53:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 17:53:24

US3032115

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:48:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-06T13:15:33', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'febfbbd4-2195-43fb-b9d8-f0874997f648' User entered 'Yes (Y)'	System	06 Aug 2020 18:16:09
	System	06 Aug 2020 18:16:09

US3032115

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:48:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-06T13:15:45', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'febfbdd4-2195-43fb-b9d8-f0874997f648' User entered '97.9'	System	06 Aug 2020 18:16:09
	System	06 Aug 2020 18:16:09

US3032115

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:48:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-06T13:15:53', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'febfbdd4-2195-43fb-b9d8-f0874997f648'	System	06 Aug 2020 18:16:09
User entered 'No (N)'	System	06 Aug 2020 18:16:09



US3032115

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:48:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-06T13:16:05', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'febfbbd4-2195-43fb-b9d8-f0874997f648' User entered '06 Aug 2020 13:16'	System	06 Aug 2020 18:16:09
	System	06 Aug 2020 18:16:09

US3032115

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '06 Aug 2020 13:05'	System	06 Aug 2020 17:53:24

US3032115

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '06 Aug 2020 15:35'	System	06 Aug 2020 17:53:24

US3032115

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
Data entry locked.	System	06 Aug 2020 17:53:24
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 17:53:24

US3032115

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:48:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55

US3032115

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:48:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55

US3032115

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:48:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55

US3032115

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:48:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55



US3032115

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:48:59

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55

US3032115

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:48:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55

US3032115

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '06 Aug 2020 16:30'	System	06 Aug 2020 17:53:24

US3032115

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 17:53:24

US3032115

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
Data entry locked.	System	06 Aug 2020 17:53:24
User entered 'Day 2'	System	06 Aug 2020 17:53:24

US3032115

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:48:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-07T20:18:47', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '04fb7fb6-53ac-46d6-8ff1-bc5618a6a607' User entered 'Yes (Y)'	System	08 Aug 2020 01:19:36
	System	08 Aug 2020 01:19:36

US3032115

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:48:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-07T20:18:59', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '04fb7fb6-53ac-46d6-8ff1-bc5618a6a607' User entered '97.2'	System	08 Aug 2020 01:19:36
	System	08 Aug 2020 01:19:36

US3032115

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:48:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-07T20:19:07', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '04fb7fb6-53ac-46d6-8ff1-bc5618a6a607'	System	08 Aug 2020 01:19:36
User entered 'No (N)'	System	08 Aug 2020 01:19:36



US3032115

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:48:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-07T20:19:33', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '04fb7fb6-53ac-46d6-8ff1-bc5618a6a607' User entered '07 Aug 2020 20:19'	System	08 Aug 2020 01:19:36
	System	08 Aug 2020 01:19:36

US3032115

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 17:53:24

US3032115

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 17:53:24

US3032115

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
Data entry locked.	System	06 Aug 2020 17:53:24
User entered 'Day 3'	System	06 Aug 2020 17:53:24

US3032115

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:48:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-08T23:45:50', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '2d551f08-f078-4166-8542-7026af0958ab' User entered 'Yes (Y)'	System	09 Aug 2020 04:46:23
	System	09 Aug 2020 04:46:23

US3032115

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:48:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-08T23:46:06', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '2d551f08-f078-4166-8542-7026af0958ab' User entered '98.7'	System	09 Aug 2020 04:46:23
	System	09 Aug 2020 04:46:23

US3032115

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:48:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-08T23:46:16', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '2d551f08-f078-4166-8542-7026af0958ab' User entered 'No (N)'	System	09 Aug 2020 04:46:23
	System	09 Aug 2020 04:46:23

US3032115

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:48:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-08T23:46:20', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '2d551f08-f078-4166-8542-7026af0958ab' User entered '08 Aug 2020 23:46'	System	09 Aug 2020 04:46:23
	System	09 Aug 2020 04:46:23



US3032115

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 17:53:24

US3032115

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 17:53:24

US3032115

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
Data entry locked.	System	06 Aug 2020 17:53:24
User entered 'Day 4'	System	06 Aug 2020 17:53:24

US3032115

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:48:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-09T18:39:34', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '957b7240-ce70-47bd-9916-18fc19bc31b2' User entered 'Yes (Y)'	System	09 Aug 2020 23:40:07
	System	09 Aug 2020 23:40:07

US3032115

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:48:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-09T18:39:50', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '957b7240-ce70-47bd-9916-18fc19bc31b2' User entered '98.6'	System	09 Aug 2020 23:40:07
	System	09 Aug 2020 23:40:07

US3032115

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:48:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-09T18:39:57', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '957b7240-ce70-47bd-9916-18fc19bc31b2'	System	09 Aug 2020 23:40:07
User entered 'No (N)'	System	09 Aug 2020 23:40:07

US3032115

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:48:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-09T18:40:01', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '957b7240-ce70-47bd-9916-18fc19bc31b2' User entered '09 Aug 2020 18:40'	System	09 Aug 2020 23:40:07
	System	09 Aug 2020 23:40:07

US3032115

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 17:53:24



US3032115

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 17:53:24

US3032115

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
Data entry locked.	System	06 Aug 2020 17:53:24
User entered 'Day 5'	System	06 Aug 2020 17:53:24

US3032115

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:48:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-11T06:33:06', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'e3ad1cfb-6b0f-4412-b6fe-3a47c1c77d5b' User entered 'Yes (Y)'	System	11 Aug 2020 11:33:36
	System	11 Aug 2020 11:33:36

US3032115

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:48:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-11T06:33:24', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'e3ad1cfb-6b0f-4412-b6fe-3a47c1c77d5b' User entered '98.3'	System	11 Aug 2020 11:33:36
	System	11 Aug 2020 11:33:36

US3032115

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:48:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-11T06:33:28', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'e3ad1cfb-6b0f-4412-b6fe-3a47c1c77d5b'	System	11 Aug 2020 11:33:36
User entered 'No (N)'	System	11 Aug 2020 11:33:36

**US3032115**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 14:48:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-11T06:33:31', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'e3ad1cfb-6b0f-4412-b6fe-3a47c1c77d5b' User entered '11 Aug 2020 06:33'	System	11 Aug 2020 11:33:36
	System	11 Aug 2020 11:33:36

US3032115

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 17:53:24

US3032115

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 17:53:24



US3032115

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
Data entry locked.	System	06 Aug 2020 17:53:24
User entered 'Day 6'	System	06 Aug 2020 17:53:24

US3032115

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:48:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-11T22:13:59', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '3e679d84-a1a7-4044-9ef9-4bbda25a5576' User entered 'Yes (Y)'	System	12 Aug 2020 03:14:32
	System	12 Aug 2020 03:14:32

US3032115

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:48:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-11T22:14:16', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '3e679d84-a1a7-4044-9ef9-4bbda25a5576' User entered '98.3'	System	12 Aug 2020 03:14:32
	System	12 Aug 2020 03:14:32

US3032115

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:48:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-11T22:14:24', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '3e679d84-a1a7-4044-9ef9-4bbda25a5576' User entered 'No (N)'	System	12 Aug 2020 03:14:32
	System	12 Aug 2020 03:14:32

US3032115

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:48:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-11T22:14:28', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '3e679d84-a1a7-4044-9ef9-4bbda25a5576' User entered '11 Aug 2020 22:14'	System	12 Aug 2020 03:14:32
	System	12 Aug 2020 03:14:32

US3032115

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 17:53:24

US3032115

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 17:53:24

US3032115

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
Data entry locked.	System	06 Aug 2020 17:53:24
User entered 'Day 7'	System	06 Aug 2020 17:53:24



US3032115

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:48:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-12T21:17:01', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '3ec0623e-1692-41f9-a609-dd5b1ddd23e7' User entered 'Yes (Y)'	System	13 Aug 2020 02:17:29
	System	13 Aug 2020 02:17:29

US3032115

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:48:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-12T21:17:20', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '3ec0623e-1692-41f9-a609-dd5b1ddd23e7' User entered '97.6'	System	13 Aug 2020 02:17:29
	System	13 Aug 2020 02:17:29

US3032115

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:48:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-12T21:17:23', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '3ec0623e-1692-41f9-a609-dd5b1ddd23e7' User entered 'No (N)'	System	13 Aug 2020 02:17:29
	System	13 Aug 2020 02:17:29

US3032115

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:48:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-12T21:17:26', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '3ec0623e-1692-41f9-a609-dd5b1ddd23e7' User entered '12 Aug 2020 21:17'	System	13 Aug 2020 02:17:29
	System	13 Aug 2020 02:17:29

US3032115

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 17:53:24

US3032115

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 17:53:24

US3032115

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
Data entry locked.	System	06 Aug 2020 17:53:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 17:53:24

US3032115

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:48:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-06T13:16:31', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'c723a8d4-0232-45e7-9147-7ccc57efd092'	System	06 Aug 2020 18:16:55
User entered 'None (1)'	System	06 Aug 2020 18:16:55



US3032115

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:48:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-06T13:16:38', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'c723a8d4-0232-45e7-9147-7ccc57efd092'	System	06 Aug 2020 18:16:55
User entered 'No (N)'	System	06 Aug 2020 18:16:55

US3032115

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:48:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-06T13:16:42', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'c723a8d4-0232-45e7-9147-7ccc57efd092'	System	06 Aug 2020 18:16:55
User entered 'No (N)'	System	06 Aug 2020 18:16:55

US3032115

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:48:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-06T13:16:49', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'c723a8d4-0232-45e7-9147-7ccc57efd092'	System	06 Aug 2020 18:16:55
User entered 'None (1)'	System	06 Aug 2020 18:16:55

US3032115

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:48:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-06T13:16:53', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'c723a8d4-0232-45e7-9147-7ccc57efd092'	System	06 Aug 2020 18:16:55
User entered '06 Aug 2020 13:16'	System	06 Aug 2020 18:16:55

US3032115

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '06 Aug 2020 13:05'	System	06 Aug 2020 17:53:24

US3032115

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '06 Aug 2020 15:35'	System	06 Aug 2020 17:53:24

US3032115

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
Data entry locked.	System	06 Aug 2020 17:53:24
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 17:53:24

US3032115

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:48:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55



US3032115

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:48:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55

US3032115

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:48:59

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)	27 Mar 2021 20:42:55

US3032115

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:48:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55

US3032115

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:48:59

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)	27 Mar 2021 20:42:55

US3032115

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:48:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55

US3032115

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:48:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55

US3032115

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '06 Aug 2020 16:30'	System	06 Aug 2020 17:53:24

US3032115

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 17:53:24



US3032115

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
Data entry locked.	System	06 Aug 2020 17:53:24
User entered 'Day 2'	System	06 Aug 2020 17:53:24

US3032115

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:48:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-07T20:20:17', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '5223ab25-c748-42ec-b937-080b723fb261'	System	08 Aug 2020 01:20:49
User entered 'Does not interfere with activity (2)'	System	08 Aug 2020 01:20:49

US3032115

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:48:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-07T20:20:22', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '5223ab25-c748-42ec-b937-080b723fb261' User entered 'No (N)'	System	08 Aug 2020 01:20:49
	System	08 Aug 2020 01:20:49

US3032115

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:48:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-07T20:20:30', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '5223ab25-c748-42ec-b937-080b723fb261' User entered 'No (N)'	System	08 Aug 2020 01:20:49
	System	08 Aug 2020 01:20:49

US3032115

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:48:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-07T20:20:42', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '5223ab25-c748-42ec-b937-080b723fb261' User entered 'None (1)'	System	08 Aug 2020 01:20:49
	System	08 Aug 2020 01:20:49

US3032115

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:48:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-07T20:20:47', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '5223ab25-c748-42ec-b937-080b723fb261' User entered '07 Aug 2020 20:20'	System	08 Aug 2020 01:20:49
	System	08 Aug 2020 01:20:49

US3032115

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 17:53:24

US3032115

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 17:53:24



US3032115

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
Data entry locked.	System	06 Aug 2020 17:53:24
User entered 'Day 3'	System	06 Aug 2020 17:53:24

US3032115

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:48:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-08T23:46:41', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '99751412-2319-4bdf-80af-8cd4be3fe264'	System	09 Aug 2020 04:47:10
User entered 'None (1)'	System	09 Aug 2020 04:47:10

US3032115

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:48:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-08T23:46:48', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '99751412-2319-4bdf-80af-8cd4be3fe264'	System	09 Aug 2020 04:47:10
User entered 'No (N)'	System	09 Aug 2020 04:47:10

US3032115

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:48:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-08T23:46:54', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '99751412-2319-4bdf-80af-8cd4be3fe264'	System	09 Aug 2020 04:47:10
User entered 'No (N)'	System	09 Aug 2020 04:47:10

US3032115

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:48:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-08T23:47:03', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '99751412-2319-4bdf-80af-8cd4be3fe264' User entered 'None (1)'	System	09 Aug 2020 04:47:10
	System	09 Aug 2020 04:47:10

US3032115

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:48:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-08T23:47:07', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '99751412-2319-4bdf-80af-8cd4be3fe264' User entered '08 Aug 2020 23:47'	System	09 Aug 2020 04:47:10
	System	09 Aug 2020 04:47:10

US3032115

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 17:53:24

US3032115

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 17:53:24



US3032115

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
Data entry locked.	System	06 Aug 2020 17:53:24
User entered 'Day 4'	System	06 Aug 2020 17:53:24

US3032115

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:48:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-09T18:40:08', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '10114429-fd0f-4412-ac3f-4315194444dd'	System	09 Aug 2020 23:40:25
User entered 'None (1)'	System	09 Aug 2020 23:40:25

US3032115

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:48:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-09T18:40:11', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '10114429-fd0f-4412-ac3f-4315194444dd' User entered 'No (N)'	System	09 Aug 2020 23:40:25
	System	09 Aug 2020 23:40:25

US3032115

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:48:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-09T18:40:16', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '10114429-fd0f-4412-ac3f-4315194444dd' User entered 'No (N)'	System	09 Aug 2020 23:40:25
	System	09 Aug 2020 23:40:25

US3032115

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:48:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-09T18:40:22', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '10114429-fd0f-4412-ac3f-4315194444dd' User entered 'None (1)'	System	09 Aug 2020 23:40:25
	System	09 Aug 2020 23:40:25

US3032115

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:48:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-09T18:40:24', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '10114429-fd0f-4412-ac3f-4315194444dd' User entered '09 Aug 2020 18:40'	System	09 Aug 2020 23:40:25
	System	09 Aug 2020 23:40:25

US3032115

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 17:53:24

US3032115

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 17:53:24



US3032115

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
Data entry locked.	System	06 Aug 2020 17:53:24
User entered 'Day 5'	System	06 Aug 2020 17:53:24

US3032115

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:48:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-11T06:33:37', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'd288ddfe-4de4-41ef-b5b3-f3cef7581c35'	System	11 Aug 2020 11:33:53
User entered 'None (1)'	System	11 Aug 2020 11:33:53

US3032115

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:48:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-11T06:33:41', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'd288ddfe-4de4-41ef-b5b3-f3cef7581c35'	System	11 Aug 2020 11:33:53
User entered 'No (N)'	System	11 Aug 2020 11:33:53

US3032115

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:48:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-11T06:33:45', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'd288ddfe-4de4-41ef-b5b3-f3cef7581c35'	System	11 Aug 2020 11:33:53
User entered 'No (N)'	System	11 Aug 2020 11:33:53

US3032115

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:48:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-11T06:33:49', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'd288ddfe-4de4-41ef-b5b3-f3cef7581c35'	System	11 Aug 2020 11:33:53
User entered 'None (1)'	System	11 Aug 2020 11:33:53

US3032115

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:48:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-11T06:33:51', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'd288ddfe-4de4-41ef-b5b3-f3cef7581c35'	System	11 Aug 2020 11:33:53
User entered '11 Aug 2020 06:33'	System	11 Aug 2020 11:33:53

US3032115

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 17:53:24

US3032115

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 17:53:24



US3032115

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
Data entry locked.	System	06 Aug 2020 17:53:24
User entered 'Day 6'	System	06 Aug 2020 17:53:24

US3032115

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:48:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-11T22:14:38', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '2d4a2aec-7053-4d88-ae38-44fe8908fa22'	System	12 Aug 2020 03:15:12
User entered 'None (1)'	System	12 Aug 2020 03:15:12

US3032115

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:48:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-11T22:14:41', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '2d4a2aec-7053-4d88-ae38-44fe8908fa22'	System	12 Aug 2020 03:15:12
User entered 'No (N)'	System	12 Aug 2020 03:15:12

US3032115

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:48:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-11T22:15:00', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '2d4a2aec-7053-4d88-ae38-44fe8908fa22'	System	12 Aug 2020 03:15:12
User entered 'No (N)'	System	12 Aug 2020 03:15:12

US3032115

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:48:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-11T22:15:04', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '2d4a2aec-7053-4d88-ae38-44fe8908fa22'	System	12 Aug 2020 03:15:12
User entered 'None (1)'	System	12 Aug 2020 03:15:12

**US3032115**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 14:48:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-11T22:15:06', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '2d4a2aec-7053-4d88-ae38-44fe8908fa22'	System	12 Aug 2020 03:15:12
User entered '11 Aug 2020 22:15'	System	12 Aug 2020 03:15:12

US3032115

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 17:53:24

US3032115

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 17:53:24



US3032115

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
Data entry locked.	System	06 Aug 2020 17:53:24
User entered 'Day 7'	System	06 Aug 2020 17:53:24

US3032115

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:48:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-12T21:17:30', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'a917c57a-96ac-4c4b-9624-88f7c4ea2a64' User entered 'None (1)'	System	13 Aug 2020 02:17:49
	System	13 Aug 2020 02:17:49

US3032115

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:48:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-12T21:17:39', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'a917c57a-96ac-4c4b-9624-88f7c4ea2a64' User entered 'No (N)'	System	13 Aug 2020 02:17:49
	System	13 Aug 2020 02:17:49

US3032115

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:48:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-12T21:17:42', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'a917c57a-96ac-4c4b-9624-88f7c4ea2a64' User entered 'No (N)'	System	13 Aug 2020 02:17:49
	System	13 Aug 2020 02:17:49

US3032115

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:48:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-12T21:17:45', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'a917c57a-96ac-4c4b-9624-88f7c4ea2a64' User entered 'None (1)'	System	13 Aug 2020 02:17:49
	System	13 Aug 2020 02:17:49

US3032115

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:48:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-12T21:17:47', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'a917c57a-96ac-4c4b-9624-88f7c4ea2a64' User entered '12 Aug 2020 21:17'	System	13 Aug 2020 02:17:49
	System	13 Aug 2020 02:17:49

US3032115

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 17:53:24

**US3032115**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 14:48:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 17:53:24



US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
Data entry locked.	System	06 Aug 2020 17:53:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 17:53:24

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:48:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-06T13:17:12', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '79924ec4-d48c-478a-ba85-1743e7e5ad68' User entered 'None (0)'	System	06 Aug 2020 18:17:43
	System	06 Aug 2020 18:17:43

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:48:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-06T13:17:17', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '79924ec4-d48c-478a-ba85-1743e7e5ad68' User entered 'None (0)'	System	06 Aug 2020 18:17:43
	System	06 Aug 2020 18:17:43

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:48:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-06T13:17:21', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '79924ec4-d48c-478a-ba85-1743e7e5ad68' User entered 'None (0)'	System	06 Aug 2020 18:17:43
	System	06 Aug 2020 18:17:43

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:48:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-06T13:17:25', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '79924ec4-d48c-478a-ba85-1743e7e5ad68' User entered 'None (0)'	System	06 Aug 2020 18:17:43
	System	06 Aug 2020 18:17:43

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:48:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-06T13:17:29', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '79924ec4-d48c-478a-ba85-1743e7e5ad68' User entered 'None (0)'	System	06 Aug 2020 18:17:43
	System	06 Aug 2020 18:17:43

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:48:59

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-06T13:17:32', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '79924ec4-d48c-478a-ba85-1743e7e5ad68' User entered 'None (0)'	System	06 Aug 2020 18:17:43
	System	06 Aug 2020 18:17:43

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:48:59

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)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-06T13:17:37', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '79924ec4-d48c-478a-ba85-1743e7e5ad68' User entered 'No (N)'	System	06 Aug 2020 18:17:43
	System	06 Aug 2020 18:17:43



US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:48:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-06T13:17:41', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '79924ec4-d48c-478a-ba85-1743e7e5ad68' User entered '06 Aug 2020 13:17'	System	06 Aug 2020 18:17:43
	System	06 Aug 2020 18:17:43

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '06 Aug 2020 13:05'	System	06 Aug 2020 17:53:24

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '06 Aug 2020 15:35'	System	06 Aug 2020 17:53:24

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
Data entry locked.	System	06 Aug 2020 17:53:24
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 17:53:24

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:48:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:48:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:48:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:48:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55



US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:48:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:48:59

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:48:59

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)	27 Mar 2021 20:42:55

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:48:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '06 Aug 2020 16:30'	System	06 Aug 2020 17:53:24

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 17:53:24

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
Data entry locked.	System	06 Aug 2020 17:53:24
User entered 'Day 2'	System	06 Aug 2020 17:53:24

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:48:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-07T20:20:57', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'b8dd1633-64c9-4ee7-80c7-1c1f1675862c' User entered 'None (0)'	System	08 Aug 2020 01:22:01
	System	08 Aug 2020 01:22:01



US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:48:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-07T20:21:01', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'b8dd1633-64c9-4ee7-80c7-1c1f1675862c' User entered 'None (0)'	System	08 Aug 2020 01:22:01
	System	08 Aug 2020 01:22:01

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:48:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-07T20:21:06', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'b8dd1633-64c9-4ee7-80c7-1c1f1675862c' User entered 'None (0)'	System	08 Aug 2020 01:22:01
	System	08 Aug 2020 01:22:01

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:48:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-07T20:21:11', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'b8dd1633-64c9-4ee7-80c7-1c1f1675862c' User entered 'None (0)'	System	08 Aug 2020 01:22:01
	System	08 Aug 2020 01:22:01

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:48:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-07T20:21:33', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'b8dd1633-64c9-4ee7-80c7-1c1f1675862c' User entered 'None (0)'	System	08 Aug 2020 01:22:01
	System	08 Aug 2020 01:22:01

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:48:59

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-07T20:21:40', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'b8dd1633-64c9-4ee7-80c7-1c1f1675862c' User entered 'None (0)'	System	08 Aug 2020 01:22:01
	System	08 Aug 2020 01:22:01

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:48:59

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)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-07T20:21:54', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'b8dd1633-64c9-4ee7-80c7-1c1f1675862c' User entered 'No (N)'	System	08 Aug 2020 01:22:01
	System	08 Aug 2020 01:22:01

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:48:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-07T20:21:57', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'b8dd1633-64c9-4ee7-80c7-1c1f1675862c' User entered '07 Aug 2020 20:21'	System	08 Aug 2020 01:22:01
	System	08 Aug 2020 01:22:01

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 17:53:24



US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 17:53:24

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
Data entry locked.	System	06 Aug 2020 17:53:24
User entered 'Day 3'	System	06 Aug 2020 17:53:24

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:48:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-08T23:47:13', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '841b5ed8-daf3-4fc5-aa16-834a5127a5fd' User entered 'None (0)'	System	09 Aug 2020 04:47:54
	System	09 Aug 2020 04:47:54

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:48:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-08T23:47:17', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '841b5ed8-daf3-4fc5-aa16-834a5127a5fd' User entered 'None (0)'	System	09 Aug 2020 04:47:54
	System	09 Aug 2020 04:47:54

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:48:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-08T23:47:21', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '841b5ed8-daf3-4fc5-aa16-834a5127a5fd' User entered 'None (0)'	System	09 Aug 2020 04:47:54
	System	09 Aug 2020 04:47:54

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:48:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-08T23:47:28', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '841b5ed8-daf3-4fc5-aa16-834a5127a5fd' User entered 'None (0)'	System	09 Aug 2020 04:47:54
	System	09 Aug 2020 04:47:54

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:48:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-08T23:47:35', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '841b5ed8-daf3-4fc5-aa16-834a5127a5fd' User entered 'None (0)'	System	09 Aug 2020 04:47:54
	System	09 Aug 2020 04:47:54

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:48:59

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-08T23:47:42', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '841b5ed8-daf3-4fc5-aa16-834a5127a5fd' User entered 'None (0)'	System	09 Aug 2020 04:47:54
	System	09 Aug 2020 04:47:54



US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:48:59

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)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-08T23:47:47', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '841b5ed8-daf3-4fc5-aa16-834a5127a5fd' User entered 'No (N)'	System	09 Aug 2020 04:47:54
	System	09 Aug 2020 04:47:54

**US3032115**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:48:59**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-08T23:47:51', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '841b5ed8-daf3-4fc5-aa16-834a5127a5fd' User entered '08 Aug 2020 23:47'	System	09 Aug 2020 04:47:54
	System	09 Aug 2020 04:47:54

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 17:53:24

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 17:53:24

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
Data entry locked.	System	06 Aug 2020 17:53:24
User entered 'Day 4'	System	06 Aug 2020 17:53:24

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:48:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-09T18:40:34', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '71177215-5952-421e-8e5f-4d7b938504d6' User entered 'None (0)'	System	09 Aug 2020 23:41:07
	System	09 Aug 2020 23:41:07

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:48:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-09T18:40:37', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '71177215-5952-421e-8e5f-4d7b938504d6' User entered 'None (0)'	System	09 Aug 2020 23:41:07
	System	09 Aug 2020 23:41:07

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:48:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-09T18:40:41', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '71177215-5952-421e-8e5f-4d7b938504d6' User entered 'None (0)'	System	09 Aug 2020 23:41:07
	System	09 Aug 2020 23:41:07



US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:48:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-09T18:40:47', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '71177215-5952-421e-8e5f-4d7b938504d6' User entered 'None (0)'	System	09 Aug 2020 23:41:07
	System	09 Aug 2020 23:41:07

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:48:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-09T18:40:51', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '71177215-5952-421e-8e5f-4d7b938504d6' User entered 'None (0)'	System	09 Aug 2020 23:41:07
	System	09 Aug 2020 23:41:07

**US3032115**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:48:59**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-09T18:40:54', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '71177215-5952-421e-8e5f-4d7b938504d6' User entered 'None (0)'	System	09 Aug 2020 23:41:07
	System	09 Aug 2020 23:41:07

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:48:59

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)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-09T18:41:01', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '71177215-5952-421e-8e5f-4d7b938504d6'	System	09 Aug 2020 23:41:07
User entered 'No (N)'	System	09 Aug 2020 23:41:07

**US3032115**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:48:59**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-09T18:41:04', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '71177215-5952-421e-8e5f-4d7b938504d6' User entered '09 Aug 2020 18:41'	System	09 Aug 2020 23:41:07
	System	09 Aug 2020 23:41:07

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 17:53:24

**US3032115**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:48:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 17:53:24

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
Data entry locked.	System	06 Aug 2020 17:53:24
User entered 'Day 5'	System	06 Aug 2020 17:53:24



US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:48:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-11T06:33:58', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'a464c94c-e337-4dfe-a7d1-1c620917e0b8' User entered 'None (0)'	System	11 Aug 2020 11:34:25
	System	11 Aug 2020 11:34:25

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:48:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-11T06:34:01', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'a464c94c-e337-4dfe-a7d1-1c620917e0b8' User entered 'None (0)'	System	11 Aug 2020 11:34:25
	System	11 Aug 2020 11:34:25

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:48:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-11T06:34:06', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'a464c94c-e337-4dfe-a7d1-1c620917e0b8' User entered 'None (0)'	System	11 Aug 2020 11:34:25
	System	11 Aug 2020 11:34:25

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:48:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-11T06:34:11', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'a464c94c-e337-4dfe-a7d1-1c620917e0b8' User entered 'None (0)'	System	11 Aug 2020 11:34:25
	System	11 Aug 2020 11:34:25

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:48:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-11T06:34:14', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'a464c94c-e337-4dfe-a7d1-1c620917e0b8' User entered 'None (0)'	System	11 Aug 2020 11:34:25
	System	11 Aug 2020 11:34:25

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:48:59

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-11T06:34:17', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'a464c94c-e337-4dfe-a7d1-1c620917e0b8' User entered 'None (0)'	System	11 Aug 2020 11:34:25
	System	11 Aug 2020 11:34:25

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:48:59

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)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-11T06:34:21', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'a464c94c-e337-4dfe-a7d1-1c620917e0b8' User entered 'No (N)'	System	11 Aug 2020 11:34:25
	System	11 Aug 2020 11:34:25

**US3032115**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:48:59**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-11T06:34:23', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'a464c94c-e337-4dfe-a7d1-1c620917e0b8' User entered '11 Aug 2020 06:34'	System	11 Aug 2020 11:34:25
	System	11 Aug 2020 11:34:25



US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 17:53:24

**US3032115**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:48:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 17:53:24

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
Data entry locked.	System	06 Aug 2020 17:53:24
User entered 'Day 6'	System	06 Aug 2020 17:53:24

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:48:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-11T22:15:10', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'f8760859-e7c6-40d5-8136-a68fe346d004' User entered 'None (0)'	System	12 Aug 2020 03:15:35
	System	12 Aug 2020 03:15:35

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:48:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-11T22:15:13', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'f8760859-e7c6-40d5-8136-a68fe346d004' User entered 'None (0)'	System	12 Aug 2020 03:15:35
	System	12 Aug 2020 03:15:35

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:48:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-11T22:15:16', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'f8760859-e7c6-40d5-8136-a68fe346d004' User entered 'None (0)'	System	12 Aug 2020 03:15:35
	System	12 Aug 2020 03:15:35

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:48:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-11T22:15:19', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'f8760859-e7c6-40d5-8136-a68fe346d004' User entered 'None (0)'	System	12 Aug 2020 03:15:35
	System	12 Aug 2020 03:15:35

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:48:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-11T22:15:21', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'f8760859-e7c6-40d5-8136-a68fe346d004' User entered 'None (0)'	System	12 Aug 2020 03:15:35
	System	12 Aug 2020 03:15:35



US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:48:59

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-11T22:15:23', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'f8760859-e7c6-40d5-8136-a68fe346d004' User entered 'None (0)'	System	12 Aug 2020 03:15:35
	System	12 Aug 2020 03:15:35

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:48:59

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)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-11T22:15:28', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'f8760859-e7c6-40d5-8136-a68fe346d004' User entered 'No (N)'	System	12 Aug 2020 03:15:35
	System	12 Aug 2020 03:15:35

**US3032115**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:48:59**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-11T22:15:32', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'f8760859-e7c6-40d5-8136-a68fe346d004'	System	12 Aug 2020 03:15:35
User entered '11 Aug 2020 22:15'	System	12 Aug 2020 03:15:35

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 17:53:24

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 17:53:24

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
Data entry locked.	System	06 Aug 2020 17:53:24
User entered 'Day 7'	System	06 Aug 2020 17:53:24

**US3032115**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:48:59**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-12T21:17:52', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '355f6bda-775e-4fbc-a925-f0d5093deb9c' User entered 'None (0)'	System	13 Aug 2020 02:18:16
	System	13 Aug 2020 02:18:16

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:48:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-12T21:17:55', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '355f6bda-775e-4fbc-a925-f0d5093deb9c' User entered 'None (0)'	System	13 Aug 2020 02:18:16
	System	13 Aug 2020 02:18:16



US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:48:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-12T21:17:57', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '355f6bda-775e-4fbc-a925-f0d5093deb9c' User entered 'None (0)'	System	13 Aug 2020 02:18:16
	System	13 Aug 2020 02:18:16

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:48:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-12T21:18:00', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '355f6bda-775e-4fbc-a925-f0d5093deb9c' User entered 'None (0)'	System	13 Aug 2020 02:18:16
	System	13 Aug 2020 02:18:16

**US3032115**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:48:59**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-12T21:18:05', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '355f6bda-775e-4fbc-a925-f0d5093deb9c' User entered 'None (0)'	System	13 Aug 2020 02:18:16
	System	13 Aug 2020 02:18:16

**US3032115**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:48:59**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-12T21:18:08', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '355f6bda-775e-4fbc-a925-f0d5093deb9c' User entered 'None (0)'	System	13 Aug 2020 02:18:16
	System	13 Aug 2020 02:18:16

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:48:59

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)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-12T21:18:11', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '355f6bda-775e-4fbc-a925-f0d5093deb9c' User entered 'No (N)'	System	13 Aug 2020 02:18:16
	System	13 Aug 2020 02:18:16

**US3032115**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:48:59**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-08-12T21:18:14', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '355f6bda-775e-4fbc-a925-f0d5093deb9c' User entered '12 Aug 2020 21:18'	System	13 Aug 2020 02:18:16
	System	13 Aug 2020 02:18:16

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 17:53:24

US3032115

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 17:53:24



US3032115

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:16:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	27 Aug 2020 14:43:25

US3032115

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:16:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered '14 Aug 2020'	(b) (4) Linden DeBoer (b) (4) (b) (4)	27 Aug 2020 14:43:25

US3032115

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:16:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	27 Aug 2020 14:43:25

US3032115

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:59

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:16:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered empty.	(b) (4) Linden DeBoer (b) (4) (b) (4)	27 Aug 2020 14:43:25

US3032115

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:48:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:17:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	27 Aug 2020 14:43:28

**US3032115**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:48:59**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
User entered 'I'	System	27 Aug 2020 14:43:28

US3032115

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:17:09
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	27 Aug 2020 14:43:43

US3032115

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:59

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:17:09
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User closed query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	28 Aug 2020 05:22:23
Query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.'	Linden DeBoer (b) (4) (b) (4)	27 Aug 2020 14:43:48
answered with 'data is correct' (Site from System).		
User opened query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	27 Aug 2020 14:43:43
User entered '24 Aug 2020'	Linden DeBoer (b) (4) (b) (4)	27 Aug 2020 14:43:43



US3032115

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:17:09
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	27 Aug 2020 14:43:43

US3032115

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:59

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:17:09
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered empty.	(b) (4) Linden DeBoer (b) (4) (b) (4)	27 Aug 2020 14:43:43

US3032115

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:48:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:21:05
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	27 Aug 2020 14:43:52

**US3032115**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:48:59**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
User entered 'I'	System	27 Aug 2020 14:43:52

US3032115

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:21:35
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 15:28:59

US3032115

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:59

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:21:35
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:24
Signature has been broken.	(b) (4) Linden DeBoer (b) (4)	18 Nov 2020 17:24:38
User entered '27 Aug 2020' reason for change: Data Entry Error	(b) (4) Linden DeBoer (b) (4)	18 Nov 2020 17:24:38
User signature succeeded.	(b) (4) Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User closed query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	03 Sep 2020 15:29:29
Query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	03 Sep 2020 15:29:29
User entered '29 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 15:29:29
User opened query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	03 Sep 2020 15:28:59
User entered '31 Aug 2020'	(b) (4), (b) (6)	03 Sep 2020 15:28:59

US3032115

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:21:35
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 15:28:59

US3032115

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:59

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:21:35
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 15:28:59



US3032115

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:48:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:21:55
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 15:29:33

**US3032115**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:48:59**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
User entered 'I'	System	03 Sep 2020 15:29:33

US3032115

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:48:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:22:09
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 15:33:28

US3032115

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:48:59

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:22:09
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered '03 Sep 2020'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 15:33:28

US3032115

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:48:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:22:09
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 15:33:28

**US3032115**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:48:59**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
User entered 'VISIT2'	System	03 Sep 2020 15:33:28

US3032115

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
User accepted default value 'Pre-Dose (PREDOSE)'		03 Sep 2020 15:34:15

US3032115

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:26:18
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 15:34:15



US3032115

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:26:18
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered '03 Sep 2020'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 15:34:15

US3032115

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:26:18
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered '08:41'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 15:34:15

US3032115

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:59

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
User entered '03 Sep 2020 08:41'	System	03 Sep 2020 15:34:15

US3032115

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:26:18
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered '36.8' C	(b) (4) (b) (4), (b) (6)	03 Sep 2020 15:34:15

US3032115

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:26:18
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 15:34:15

US3032115

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:26:18
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 15:34:15

US3032115

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:26:18
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered '67'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 15:34:15

US3032115

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
User entered 'bpm'	System	03 Sep 2020 15:34:15



US3032115

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:26:18
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered '16'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 15:34:15

US3032115

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
User entered 'breaths/min'	System	03 Sep 2020 15:34:15

US3032115

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:26:18
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered '137'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 15:34:15

US3032115

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
User entered 'mmHg'	System	03 Sep 2020 15:34:15

US3032115

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:26:18
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered '89'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 15:34:15

US3032115

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:48:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
User entered 'mmHg'	System	03 Sep 2020 15:34:15

US3032115

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
User accepted default value 'Post-Dose (POSTDOSE)'		03 Sep 2020 15:34:15

US3032115

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:26:18
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Sep 2020 21:01:17
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 21:01:17
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 15:34:15
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 15:34:15



US3032115

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:26:18
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered '03 Sep 2020' reason for change: Data Entry Error	(b) (4)	03 Sep 2020 21:01:17
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 15:34:15

**US3032115**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:48:59**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:26:18
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered '10:54' reason for change: Data Entry Error	(b) (4)	03 Sep 2020 21:01:17
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 15:34:15

US3032115

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:59

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
User entered '03 Sep 2020 10:54'	System	03 Sep 2020 21:01:17
User entered empty.	System	03 Sep 2020 15:34:15

US3032115

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:26:18
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered '36.6' C reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	03 Sep 2020 21:01:17
User entered empty.		03 Sep 2020 15:34:15

US3032115

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:26:18
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4)	03 Sep 2020 21:01:17
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 15:34:15

US3032115

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:26:18
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 15:34:15

US3032115

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:26:18
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered '61' reason for change: Data Entry Error	(b) (4)	03 Sep 2020 21:01:17
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 15:34:15

US3032115

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
User entered 'bpm'	System	03 Sep 2020 21:01:17
User entered empty.	System	03 Sep 2020 15:34:15



US3032115

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:26:18
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered '14' reason for change: Data Entry Error	(b) (4)	03 Sep 2020 21:01:17
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 15:34:15

US3032115

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
User entered 'breaths/min'	System	03 Sep 2020 21:01:17
User entered empty.	System	03 Sep 2020 15:34:15

US3032115

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:26:18
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered '132' reason for change: Data Entry Error	(b) (4)	03 Sep 2020 21:01:17
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 15:34:15

US3032115

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
User entered 'mmHg'	System	03 Sep 2020 21:01:17
User entered empty.	System	03 Sep 2020 15:34:15

US3032115

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:59

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:26:18
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered '78' reason for change: Data Entry Error	(b) (4)	
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 21:01:17
		03 Sep 2020 15:34:15

US3032115

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:48:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
User entered 'mmHg'	System	03 Sep 2020 21:01:17
User entered empty.	System	03 Sep 2020 15:34:15

US3032115

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:48:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:26:22
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 15:34:25

US3032115

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:48:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:26:22
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered '03 Sep 2020'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 15:34:25



US3032115

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:48:59

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 15:34:47

US3032115

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:48:59

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 15:34:47

US3032115

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:48:59

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)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 15:34:47

US3032115

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:48:59

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
User entered 'MRNA-1273 OR PLACEBO'	System	03 Sep 2020 15:34:47

US3032115

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:48:59

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered '03 Sep 2020'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 15:34:47

US3032115

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:48:59

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered '10:21'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 15:34:47

US3032115

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:48:59

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
User entered '03 Sep 2020 10:21'	System	03 Sep 2020 15:34:47

US3032115

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:48:59

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:26:43
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 15:34:47



US3032115

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:48:59

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:26:43
User entered 'ONCE'	System	03 Sep 2020 15:34:47

US3032115

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:48:59

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
User entered 'INTRAMUSCULAR'	System	03 Sep 2020 15:34:47

US3032115

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:48:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:26:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 15:35:05

US3032115

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:48:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:26:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered '03 Sep 2020'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 15:35:05

US3032115

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:48:59

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:26:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered '09:35'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 15:35:05

**US3032115**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:48:59**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
User entered '03 Sep 2020 09:35'	System	03 Sep 2020 15:35:05

US3032115

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:48:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:28:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered '03 Sep 2020'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 15:35:20

**US3032115**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 14:48:59**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	03 Sep 2020 15:35:20



US3032115

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:48:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:28:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 15:35:20

**US3032115**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 14:48:59**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:28:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered '08:57'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 15:35:20

**US3032115**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 14:48:59**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
User entered '03 Sep 2020 08:57'	System	03 Sep 2020 15:35:20

US3032115

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:48:59

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	03 Sep 2020 15:35:20

US3032115

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:48:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:28:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 15:35:20

US3032115

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:48:59

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:28:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 15:35:20

**US3032115**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 14:48:59**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
User entered empty.	System	03 Sep 2020 15:35:20

US3032115

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:48:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:28:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 15:35:23



**US3032115**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:48:59**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
User entered 'I'	System	03 Sep 2020 15:35:23

US3032115

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
Data entry locked.	System	03 Sep 2020 15:34:47
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 15:34:47

US3032115

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:48:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-03T10:53:48', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'a60fbeb7-3bdc-4d7c-a336-252e7e739af0' User entered 'Yes (Y)'	System	03 Sep 2020 15:54:11
	System	03 Sep 2020 15:54:11

US3032115

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:48:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-03T10:53:58', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'a60fbeb7-3bdc-4d7c-a336-252e7e739af0' User entered '97.9'	System	03 Sep 2020 15:54:11
	System	03 Sep 2020 15:54:11

US3032115

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:48:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-03T10:54:03', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'a60fbeb7-3bdc-4d7c-a336-252e7e739af0' User entered 'No (N)'	System	03 Sep 2020 15:54:11
	System	03 Sep 2020 15:54:11

**US3032115**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 14:48:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-03T10:54:08', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'a60fbeb7-3bdc-4d7c-a336-252e7e739af0' User entered '03 Sep 2020 10:54'	System	03 Sep 2020 15:54:11
	System	03 Sep 2020 15:54:11

US3032115

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '03 Sep 2020 10:41'	System	03 Sep 2020 15:34:47

US3032115

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '03 Sep 2020 13:11'	System	03 Sep 2020 15:34:47



US3032115

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
Data entry locked.	System	03 Sep 2020 15:34:47
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 15:34:47

US3032115

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:48:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-03T17:34:03', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'd7fdc09a-8b54-43be-be66-76f3ec65c9e2'	System	03 Sep 2020 22:35:05
User entered 'Yes (Y)'	System	03 Sep 2020 22:35:05

US3032115

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:48:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-03T17:34:13', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'd7fdc09a-8b54-43be-be66-76f3ec65c9e2' User entered '98.7'	System	03 Sep 2020 22:35:05
	System	03 Sep 2020 22:35:05

US3032115

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:48:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-03T17:34:19', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'd7fdc09a-8b54-43be-be66-76f3ec65c9e2'	System	03 Sep 2020 22:35:05
User entered 'No (N)'	System	03 Sep 2020 22:35:05

US3032115

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:48:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-03T17:34:23', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'd7fdc09a-8b54-43be-be66-76f3ec65c9e2' User entered '03 Sep 2020 17:34'	System	03 Sep 2020 22:35:05
	System	03 Sep 2020 22:35:05

US3032115

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '03 Sep 2020 14:06'	System	03 Sep 2020 15:34:47

US3032115

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 15:34:47

US3032115

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
Data entry locked.	System	03 Sep 2020 15:34:47
User entered 'Day 2'	System	03 Sep 2020 15:34:47



US3032115

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:48:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-04T18:58:11', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'ce976fd6-09e4-414b-9af0-14c89f91ace8' User entered 'Yes (Y)'	System	04 Sep 2020 23:58:27
	System	04 Sep 2020 23:58:27

US3032115

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:48:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-04T18:58:16', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'ce976fd6-09e4-414b-9af0-14c89f91ace8' User entered '97.7'	System	04 Sep 2020 23:58:27
	System	04 Sep 2020 23:58:27

US3032115

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:48:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-04T18:58:20', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'ce976fd6-09e4-414b-9af0-14c89f91ace8' User entered 'No (N)'	System	04 Sep 2020 23:58:27
	System	04 Sep 2020 23:58:27

US3032115

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:48:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-04T18:58:23', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'ce976fd6-09e4-414b-9af0-14c89f91ace8' User entered '04 Sep 2020 18:58'	System	04 Sep 2020 23:58:27
	System	04 Sep 2020 23:58:27

US3032115

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 15:34:47

US3032115

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 15:34:47

US3032115

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
Data entry locked.	System	03 Sep 2020 15:34:47
User entered 'Day 3'	System	03 Sep 2020 15:34:47

US3032115

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:48:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-06T06:25:16', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '4cb5b8dc-0188-4248-b0be-a0487c8d6185' User entered 'Yes (Y)'	System	06 Sep 2020 11:25:57
	System	06 Sep 2020 11:25:57



US3032115

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:48:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-06T06:25:28', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '4cb5b8dc-0188-4248-b0be-a0487c8d6185' User entered '98.7'	System	06 Sep 2020 11:25:57
	System	06 Sep 2020 11:25:57

US3032115

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:48:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-06T06:25:33', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '4cb5b8dc-0188-4248-b0be-a0487c8d6185'	System	06 Sep 2020 11:25:57
User entered 'No (N)'	System	06 Sep 2020 11:25:57

**US3032115**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 14:48:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-06T06:25:37', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '4cb5b8dc-0188-4248-b0be-a0487c8d6185' User entered '06 Sep 2020 06:25'	System	06 Sep 2020 11:25:57
	System	06 Sep 2020 11:25:57

US3032115

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 15:34:47

US3032115

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 15:34:47

US3032115

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
Data entry locked.	System	03 Sep 2020 15:34:47
User entered 'Day 4'	System	03 Sep 2020 15:34:47

US3032115

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:48:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-06T22:21:19', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '1a5c6d83-4731-4964-bab8-b53b87e4ec04' User entered 'Yes (Y)'	System	07 Sep 2020 03:21:45
	System	07 Sep 2020 03:21:45

US3032115

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:48:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-06T22:21:31', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '1a5c6d83-4731-4964-bab8-b53b87e4ec04' User entered '98.4'	System	07 Sep 2020 03:21:45
	System	07 Sep 2020 03:21:45



US3032115

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:48:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-06T22:21:36', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '1a5c6d83-4731-4964-bab8-b53b87e4ec04' User entered 'No (N)'	System	07 Sep 2020 03:21:45
	System	07 Sep 2020 03:21:45

US3032115

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:48:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-06T22:21:39', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '1a5c6d83-4731-4964-bab8-b53b87e4ec04' User entered '06 Sep 2020 22:21'	System	07 Sep 2020 03:21:45
	System	07 Sep 2020 03:21:45

US3032115

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 15:34:47

US3032115

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 15:34:47

US3032115

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
Data entry locked.	System	03 Sep 2020 15:34:47
User entered 'Day 5'	System	03 Sep 2020 15:34:47

US3032115

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:48:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-08T07:35:37', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '2e688718-2309-4631-8fc1-e173432a1d92' User entered 'Yes (Y)'	System	08 Sep 2020 12:36:01
	System	08 Sep 2020 12:36:01

US3032115

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:48:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-08T07:35:49', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '2e688718-2309-4631-8fc1-e173432a1d92' User entered '97.7'	System	08 Sep 2020 12:36:01
	System	08 Sep 2020 12:36:01

US3032115

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:48:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-08T07:35:55', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '2e688718-2309-4631-8fc1-e173432a1d92'	System	08 Sep 2020 12:36:01
User entered 'No (N)'	System	08 Sep 2020 12:36:01



**US3032115**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 14:48:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-08T07:35:59', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '2e688718-2309-4631-8fc1-e173432a1d92' User entered '08 Sep 2020 07:35'	System	08 Sep 2020 12:36:01
	System	08 Sep 2020 12:36:01

US3032115

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 15:34:47

US3032115

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 15:34:47

US3032115

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
Data entry locked.	System	03 Sep 2020 15:34:47
User entered 'Day 6'	System	03 Sep 2020 15:34:47

US3032115

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:48:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-08T18:32:19', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '658cdf0-e00b-4499-a557-6f0d578e4bc7' User entered 'Yes (Y)'	System	08 Sep 2020 23:32:50
	System	08 Sep 2020 23:32:50

US3032115

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:48:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-08T18:32:37', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '658cdf0-e00b-4499-a557-6f0d578e4bc7' User entered '97.7'	System	08 Sep 2020 23:32:50
	System	08 Sep 2020 23:32:50

US3032115

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:48:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-08T18:32:45', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '658cdff0-e00b-4499-a557-6f0d578e4bc7'	System	08 Sep 2020 23:32:50
User entered 'No (N)'	System	08 Sep 2020 23:32:50

**US3032115**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 14:48:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-08T18:32:48', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '658cdf0-e00b-4499-a557-6f0d578e4bc7' User entered '08 Sep 2020 18:32'	System	08 Sep 2020 23:32:50
	System	08 Sep 2020 23:32:50



US3032115

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 15:34:47

US3032115

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 15:34:47

US3032115

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
Data entry locked.	System	03 Sep 2020 15:34:47
User entered 'Day 7'	System	03 Sep 2020 15:34:47

US3032115

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:48:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-09T18:26:04', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '51a202a9-91e6-4fcc-8e25-b45303c0dfcd' User entered 'Yes (Y)'	System	09 Sep 2020 23:26:23
	System	09 Sep 2020 23:26:23

US3032115

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:48:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-09T18:26:13', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '51a202a9-91e6-4fcc-8e25-b45303c0dfcd' User entered '98.8'	System	09 Sep 2020 23:26:23
	System	09 Sep 2020 23:26:23

US3032115

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:48:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-09T18:26:17', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '51a202a9-91e6-4fcc-8e25-b45303c0dfcd' User entered 'No (N)'	System	09 Sep 2020 23:26:23
	System	09 Sep 2020 23:26:23

US3032115

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:48:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-09T18:26:20', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '51a202a9-91e6-4fcc-8e25-b45303c0dfcd' User entered '09 Sep 2020 18:26'	System	09 Sep 2020 23:26:23
	System	09 Sep 2020 23:26:23

US3032115

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 15:34:47



US3032115

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 15:34:47

US3032115

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
Data entry locked.	System	03 Sep 2020 15:34:47
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 15:34:47

US3032115

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:48:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-03T10:54:24', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '2995c227-6c49-400c-a801-d738c8fd2fe1' User entered 'None (1)'	System	03 Sep 2020 15:54:39
	System	03 Sep 2020 15:54:39

US3032115

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:48:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-03T10:54:27', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '2995c227-6c49-400c-a801-d738c8fd2fe1' User entered 'No (N)'	System	03 Sep 2020 15:54:39
	System	03 Sep 2020 15:54:39

US3032115

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:48:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-03T10:54:30', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '2995c227-6c49-400c-a801-d738c8fd2fe1' User entered 'No (N)'	System	03 Sep 2020 15:54:39
	System	03 Sep 2020 15:54:39

US3032115

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:48:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-03T10:54:34', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '2995c227-6c49-400c-a801-d738c8fd2fe1' User entered 'None (1)'	System	03 Sep 2020 15:54:39
	System	03 Sep 2020 15:54:39

US3032115

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:48:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-03T10:54:37', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '2995c227-6c49-400c-a801-d738c8fd2fe1' User entered '03 Sep 2020 10:54'	System	03 Sep 2020 15:54:39
	System	03 Sep 2020 15:54:39

US3032115

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '03 Sep 2020 10:41'	System	03 Sep 2020 15:34:47



**US3032115**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 14:48:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '03 Sep 2020 13:11'	System	03 Sep 2020 15:34:47

US3032115

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
Data entry locked.	System	03 Sep 2020 15:34:47
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 15:34:47

US3032115

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:48:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-03T17:34:39', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'd4ee386d-a2a1-40d5-8162-2957791687a5' User entered 'None (1)'	System	04 Sep 2020 23:58:14
	System	04 Sep 2020 23:58:14

US3032115

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:48:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-03T17:34:47', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'd4ee386d-a2a1-40d5-8162-2957791687a5' User entered 'No (N)'	System	04 Sep 2020 23:58:14
	System	04 Sep 2020 23:58:14

US3032115

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:48:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-03T17:34:58', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'd4ee386d-a2a1-40d5-8162-2957791687a5' User entered 'No (N)'	System	04 Sep 2020 23:58:14
	System	04 Sep 2020 23:58:14

US3032115

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:48:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-03T17:35:03', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'd4ee386d-a2a1-40d5-8162-2957791687a5' User entered 'None (1)'	System	04 Sep 2020 23:58:14
	System	04 Sep 2020 23:58:14

**US3032115**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 14:48:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-03T17:35:08', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'd4ee386d-a2a1-40d5-8162-2957791687a5' User entered '03 Sep 2020 17:35'	System	04 Sep 2020 23:58:14
	System	04 Sep 2020 23:58:14

US3032115

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '03 Sep 2020 14:06'	System	03 Sep 2020 15:34:47



US3032115

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 15:34:47

US3032115

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
Data entry locked.	System	03 Sep 2020 15:34:47
User entered 'Day 2'	System	03 Sep 2020 15:34:47

US3032115

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:48:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-04T18:58:37', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '58065a94-a0e4-4f93-bef3-23b0d7fc912e' User entered 'Does not interfere with activity (2)'	System	05 Sep 2020 00:01:40
	System	05 Sep 2020 00:01:40

US3032115

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:48:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-04T18:58:42', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '58065a94-a0e4-4f93-bef3-23b0d7fc912e' User entered 'No (N)'	System	05 Sep 2020 00:01:40
	System	05 Sep 2020 00:01:40

US3032115

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:48:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-04T19:00:50', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '58065a94-a0e4-4f93-bef3-23b0d7fc912e' User entered 'Yes (Y)'	System	05 Sep 2020 00:01:40
	System	05 Sep 2020 00:01:40

US3032115

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:48:59

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)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-04T19:01:33', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '58065a94-a0e4-4f93-bef3-23b0d7fc912e' User entered '508'	System	05 Sep 2020 00:01:40
	System	05 Sep 2020 00:01:40

US3032115

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:48:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-04T19:01:00', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '58065a94-a0e4-4f93-bef3-23b0d7fc912e' User entered 'Does not interfere with activity (2)'	System	05 Sep 2020 00:01:40
	System	05 Sep 2020 00:01:40

**US3032115**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 14:48:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-04T19:01:38', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '58065a94-a0e4-4f93-bef3-23b0d7fc912e' User entered '04 Sep 2020 19:01'	System	05 Sep 2020 00:01:40
	System	05 Sep 2020 00:01:40



US3032115

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 15:34:47

US3032115

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 15:34:47

US3032115

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
Data entry locked.	System	03 Sep 2020 15:34:47
User entered 'Day 3'	System	03 Sep 2020 15:34:47

US3032115

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:48:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-06T06:25:51', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '94b0e453-589e-45b7-9f3d-78b1bace2c1c' User entered 'Does not interfere with activity (2)'	System	06 Sep 2020 11:26:50
	System	06 Sep 2020 11:26:50

US3032115

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:48:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-06T06:25:56', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '94b0e453-589e-45b7-9f3d-78b1bace2c1c' User entered 'No (N)'	System	06 Sep 2020 11:26:50
	System	06 Sep 2020 11:26:50

US3032115

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:48:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-06T06:26:11', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '94b0e453-589e-45b7-9f3d-78b1bace2c1c' User entered 'Yes (Y)'	System	06 Sep 2020 11:26:50
	System	06 Sep 2020 11:26:50

US3032115

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:48:59

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)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-06T06:26:39', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '94b0e453-589e-45b7-9f3d-78b1bace2c1c' User entered '48'	System	06 Sep 2020 11:26:50
	System	06 Sep 2020 11:26:50

US3032115

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:48:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-06T06:26:44', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '94b0e453-589e-45b7-9f3d-78b1bace2c1c' User entered 'None (1)'	System	06 Sep 2020 11:26:50
	System	06 Sep 2020 11:26:50



US3032115

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:48:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-06T06:26:47', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '94b0e453-589e-45b7-9f3d-78b1bace2c1c' User entered '06 Sep 2020 06:26'	System	06 Sep 2020 11:26:50
	System	06 Sep 2020 11:26:50

US3032115

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 15:34:47

US3032115

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 15:34:47

US3032115

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
Data entry locked.	System	03 Sep 2020 15:34:47
User entered 'Day 4'	System	03 Sep 2020 15:34:47

US3032115

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:48:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-06T22:22:05', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '7aecf417-8adf-4984-9302-3f9638710561'	System	07 Sep 2020 03:22:30
User entered 'None (1)'	System	07 Sep 2020 03:22:30

US3032115

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:48:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-06T22:22:08', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '7aecf417-8adf-4984-9302-3f9638710561' User entered 'No (N)'	System	07 Sep 2020 03:22:30
	System	07 Sep 2020 03:22:30

US3032115

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:48:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-06T22:22:21', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '7aecf417-8adf-4984-9302-3f9638710561' User entered 'No (N)'	System	07 Sep 2020 03:22:30
	System	07 Sep 2020 03:22:30

US3032115

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:48:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-06T22:22:25', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '7aecf417-8adf-4984-9302-3f9638710561' User entered 'None (1)'	System	07 Sep 2020 03:22:30
	System	07 Sep 2020 03:22:30



US3032115

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:48:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-06T22:22:27', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '7aecf417-8adf-4984-9302-3f9638710561' User entered '06 Sep 2020 22:22'	System	07 Sep 2020 03:22:30
	System	07 Sep 2020 03:22:30

US3032115

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 15:34:47

**US3032115**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 14:48:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 15:34:47

US3032115

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
Data entry locked.	System	03 Sep 2020 15:34:47
User entered 'Day 5'	System	03 Sep 2020 15:34:47

US3032115

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:48:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-08T07:36:08', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '75ded16d-e369-4b37-903a-2b54442f187a' User entered 'None (1)'	System	08 Sep 2020 12:36:33
	System	08 Sep 2020 12:36:33

US3032115

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:48:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-08T07:36:18', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '75ded16d-e369-4b37-903a-2b54442f187a' User entered 'No (N)'	System	08 Sep 2020 12:36:33
	System	08 Sep 2020 12:36:33

US3032115

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:48:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-08T07:36:26', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '75ded16d-e369-4b37-903a-2b54442f187a' User entered 'No (N)'	System	08 Sep 2020 12:36:33
	System	08 Sep 2020 12:36:33

US3032115

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:48:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-08T07:36:29', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '75ded16d-e369-4b37-903a-2b54442f187a' User entered 'None (1)'	System	08 Sep 2020 12:36:33
	System	08 Sep 2020 12:36:33



**US3032115**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 14:48:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-08T07:36:31', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '75ded16d-e369-4b37-903a-2b54442f187a' User entered '08 Sep 2020 07:36'	System	08 Sep 2020 12:36:33
	System	08 Sep 2020 12:36:33

US3032115

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 15:34:47

**US3032115**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 14:48:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 15:34:47

US3032115

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
Data entry locked.	System	03 Sep 2020 15:34:47
User entered 'Day 6'	System	03 Sep 2020 15:34:47

US3032115

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:48:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-08T18:32:53', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '425d0e1e-7fdc-4683-9bbe-a401f0ec1d6c' User entered 'None (1)'	System	08 Sep 2020 23:33:05
	System	08 Sep 2020 23:33:05

US3032115

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:48:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-08T18:32:55', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '425d0e1e-7fdc-4683-9bbe-a401f0ec1d6c' User entered 'No (N)'	System	08 Sep 2020 23:33:05
	System	08 Sep 2020 23:33:05

US3032115

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:48:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-08T18:32:58', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '425d0e1e-7fdc-4683-9bbe-a401f0ec1d6c' User entered 'No (N)'	System	08 Sep 2020 23:33:05
	System	08 Sep 2020 23:33:05

US3032115

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:48:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-08T18:33:00', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '425d0e1e-7fdc-4683-9bbe-a401f0ec1d6c' User entered 'None (1)'	System	08 Sep 2020 23:33:05
	System	08 Sep 2020 23:33:05



**US3032115**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 14:48:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-08T18:33:02', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '425d0e1e-7fdc-4683-9bbe-a401f0ec1d6c' User entered '08 Sep 2020 18:33'	System	08 Sep 2020 23:33:05
	System	08 Sep 2020 23:33:05

US3032115

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 15:34:47

**US3032115**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 14:48:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 15:34:47

US3032115

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
Data entry locked.	System	03 Sep 2020 15:34:47
User entered 'Day 7'	System	03 Sep 2020 15:34:47

US3032115

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:48:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-09T18:26:25', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '5103ecf8-408b-4979-8230-f07512d15f8c' User entered 'None (1)'	System	09 Sep 2020 23:26:39
	System	09 Sep 2020 23:26:39

US3032115

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:48:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-09T18:26:28', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '5103ecf8-408b-4979-8230-f07512d15f8c' User entered 'No (N)'	System	09 Sep 2020 23:26:39
	System	09 Sep 2020 23:26:39

US3032115

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:48:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-09T18:26:31', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '5103ecf8-408b-4979-8230-f07512d15f8c' User entered 'No (N)'	System	09 Sep 2020 23:26:39
	System	09 Sep 2020 23:26:39

US3032115

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:48:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-09T18:26:34', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '5103ecf8-408b-4979-8230-f07512d15f8c' User entered 'None (1)'	System	09 Sep 2020 23:26:39
	System	09 Sep 2020 23:26:39



US3032115

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:48:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-09T18:26:37', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '5103ecf8-408b-4979-8230-f07512d15f8c' User entered '09 Sep 2020 18:26'	System	09 Sep 2020 23:26:39
	System	09 Sep 2020 23:26:39

US3032115

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 15:34:47

**US3032115**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 14:48:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 15:34:47

US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
Data entry locked.	System	03 Sep 2020 15:34:47
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 15:34:47

US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:48:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-03T10:54:43', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '1e20d77a-3716-4021-bf55-3c9ce429c602' User entered 'None (0)'	System	03 Sep 2020 15:55:06
	System	03 Sep 2020 15:55:06

US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:48:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-03T10:54:46', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '1e20d77a-3716-4021-bf55-3c9ce429c602' User entered 'None (0)'	System	03 Sep 2020 15:55:06
	System	03 Sep 2020 15:55:06

US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:48:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-03T10:54:49', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '1e20d77a-3716-4021-bf55-3c9ce429c602' User entered 'None (0)'	System	03 Sep 2020 15:55:06
	System	03 Sep 2020 15:55:06

US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:48:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-03T10:54:51', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '1e20d77a-3716-4021-bf55-3c9ce429c602' User entered 'None (0)'	System	03 Sep 2020 15:55:06
	System	03 Sep 2020 15:55:06



US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:48:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-03T10:54:54', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '1e20d77a-3716-4021-bf55-3c9ce429c602' User entered 'None (0)'	System	03 Sep 2020 15:55:06
	System	03 Sep 2020 15:55:06

US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:48:59

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-03T10:54:57', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '1e20d77a-3716-4021-bf55-3c9ce429c602' User entered 'None (0)'	System	03 Sep 2020 15:55:06
	System	03 Sep 2020 15:55:06

US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:48:59

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)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-03T10:55:00', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '1e20d77a-3716-4021-bf55-3c9ce429c602' User entered 'No (N)'	System	03 Sep 2020 15:55:06
	System	03 Sep 2020 15:55:06

**US3032115**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:48:59**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-03T10:55:03', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '1e20d77a-3716-4021-bf55-3c9ce429c602' User entered '03 Sep 2020 10:55'	System	03 Sep 2020 15:55:06
	System	03 Sep 2020 15:55:06

US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '03 Sep 2020 10:41'	System	03 Sep 2020 15:34:47

US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '03 Sep 2020 13:11'	System	03 Sep 2020 15:34:47

US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
Data entry locked.	System	03 Sep 2020 15:34:47
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 15:34:47

**US3032115**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:48:59**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-03T17:35:20', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '592c379c-7f42-4295-9d69-345020f3d324' User entered 'None (0)'	System	04 Sep 2020 23:58:14
	System	04 Sep 2020 23:58:14



US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:48:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-03T17:35:23', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '592c379c-7f42-4295-9d69-345020f3d324' User entered 'None (0)'	System	04 Sep 2020 23:58:14
	System	04 Sep 2020 23:58:14

US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:48:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-03T17:35:27', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '592c379c-7f42-4295-9d69-345020f3d324' User entered 'None (0)'	System	04 Sep 2020 23:58:14
	System	04 Sep 2020 23:58:14

US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:48:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-03T17:35:32', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '592c379c-7f42-4295-9d69-345020f3d324' User entered 'None (0)'	System	04 Sep 2020 23:58:14
	System	04 Sep 2020 23:58:14

US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:48:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-03T17:35:35', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '592c379c-7f42-4295-9d69-345020f3d324' User entered 'None (0)'	System	04 Sep 2020 23:58:14
	System	04 Sep 2020 23:58:14

**US3032115**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:48:59**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-03T17:35:38', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '592c379c-7f42-4295-9d69-345020f3d324' User entered 'None (0)'	System	04 Sep 2020 23:58:14
	System	04 Sep 2020 23:58:14

US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:48:59

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)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-03T17:35:42', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '592c379c-7f42-4295-9d69-345020f3d324' User entered 'No (N)'	System	04 Sep 2020 23:58:14
	System	04 Sep 2020 23:58:14

**US3032115**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:48:59**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-03T17:35:45', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '592c379c-7f42-4295-9d69-345020f3d324' User entered '03 Sep 2020 17:35'	System	04 Sep 2020 23:58:14
	System	04 Sep 2020 23:58:14

US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '03 Sep 2020 14:06'	System	03 Sep 2020 15:34:47



US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 15:34:47

US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
Data entry locked.	System	03 Sep 2020 15:34:47
User entered 'Day 2'	System	03 Sep 2020 15:34:47

US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:48:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-04T19:01:45', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '3c21578a-3c2a-4ae2-a6d7-2a19598e4c17' User entered 'None (0)'	System	05 Sep 2020 00:02:35
	System	05 Sep 2020 00:02:35

**US3032115**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:48:59**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-04T19:02:07', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '3c21578a-3c2a-4ae2-a6d7-2a19598e4c17' User entered 'None (0)'	System	05 Sep 2020 00:02:35
	System	05 Sep 2020 00:02:35

US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:48:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-04T19:02:13', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '3c21578a-3c2a-4ae2-a6d7-2a19598e4c17' User entered 'None (0)'	System	05 Sep 2020 00:02:35
	System	05 Sep 2020 00:02:35

US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:48:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-04T19:02:17', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '3c21578a-3c2a-4ae2-a6d7-2a19598e4c17' User entered 'None (0)'	System	05 Sep 2020 00:02:35
	System	05 Sep 2020 00:02:35

US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:48:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-04T19:02:20', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '3c21578a-3c2a-4ae2-a6d7-2a19598e4c17' User entered 'None (0)'	System	05 Sep 2020 00:02:35
	System	05 Sep 2020 00:02:35

US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:48:59

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-04T19:02:23', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '3c21578a-3c2a-4ae2-a6d7-2a19598e4c17' User entered 'None (0)'	System	05 Sep 2020 00:02:35
	System	05 Sep 2020 00:02:35



US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:48:59

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)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-04T19:02:28', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '3c21578a-3c2a-4ae2-a6d7-2a19598e4c17' User entered 'No (N)'	System	05 Sep 2020 00:02:35
	System	05 Sep 2020 00:02:35

**US3032115**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:48:59**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-04T19:02:30', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '3c21578a-3c2a-4ae2-a6d7-2a19598e4c17' User entered '04 Sep 2020 19:02'	System	05 Sep 2020 00:02:35
	System	05 Sep 2020 00:02:35

US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 15:34:47

US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 15:34:47

US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
Data entry locked.	System	03 Sep 2020 15:34:47
User entered 'Day 3'	System	03 Sep 2020 15:34:47

US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:48:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-06T06:26:52', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '0ff8e9dc-fa92-4d02-aa33-3f027fe56180' User entered 'None (0)'	System	07 Sep 2020 03:21:33
	System	07 Sep 2020 03:21:33

US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:48:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-06T06:26:54', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '0ff8e9dc-fa92-4d02-aa33-3f027fe56180' User entered 'None (0)'	System	07 Sep 2020 03:21:33
	System	07 Sep 2020 03:21:33

US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:48:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-06T06:26:59', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '0ff8e9dc-fa92-4d02-aa33-3f027fe56180' User entered 'None (0)'	System	07 Sep 2020 03:21:33
	System	07 Sep 2020 03:21:33



US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:48:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-06T06:27:04', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '0ff8e9dc-fa92-4d02-aa33-3f027fe56180' User entered 'None (0)'	System	07 Sep 2020 03:21:33
	System	07 Sep 2020 03:21:33

US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:48:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-06T06:27:07', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '0ff8e9dc-fa92-4d02-aa33-3f027fe56180' User entered 'None (0)'	System	07 Sep 2020 03:21:33
	System	07 Sep 2020 03:21:33

US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:48:59

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-06T06:27:10', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '0ff8e9dc-fa92-4d02-aa33-3f027fe56180' User entered 'None (0)'	System	07 Sep 2020 03:21:33
	System	07 Sep 2020 03:21:33

US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:48:59

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)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-06T06:27:13', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '0ff8e9dc-fa92-4d02-aa33-3f027fe56180' User entered 'No (N)'	System	07 Sep 2020 03:21:33
	System	07 Sep 2020 03:21:33

**US3032115**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:48:59**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-06T06:27:16', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '0ff8e9dc-fa92-4d02-aa33-3f027fe56180' User entered '06 Sep 2020 06:27'	System	07 Sep 2020 03:21:33
	System	07 Sep 2020 03:21:33

US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 15:34:47

**US3032115**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:48:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 15:34:47

US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
Data entry locked.	System	03 Sep 2020 15:34:47
User entered 'Day 4'	System	03 Sep 2020 15:34:47



US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:48:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-06T22:22:31', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '9b74aef2-7ace-43a0-a0fc-ea0135c04ecc' User entered 'None (0)'	System	07 Sep 2020 03:22:57
	System	07 Sep 2020 03:22:57

US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:48:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-06T22:22:33', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '9b74aef2-7ace-43a0-a0fc-ea0135c04ecc' User entered 'None (0)'	System	07 Sep 2020 03:22:57
	System	07 Sep 2020 03:22:57

US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:48:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-06T22:22:36', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '9b74aef2-7ace-43a0-a0fc-ea0135c04ecc' User entered 'None (0)'	System	07 Sep 2020 03:22:57
	System	07 Sep 2020 03:22:57

US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:48:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-06T22:22:40', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '9b74aef2-7ace-43a0-a0fc-ea0135c04ecc' User entered 'None (0)'	System	07 Sep 2020 03:22:57
	System	07 Sep 2020 03:22:57

US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:48:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-06T22:22:43', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '9b74aef2-7ace-43a0-a0fc-ea0135c04ecc' User entered 'None (0)'	System	07 Sep 2020 03:22:57
	System	07 Sep 2020 03:22:57

US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:48:59

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-06T22:22:45', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '9b74aef2-7ace-43a0-a0fc-ea0135c04ecc' User entered 'None (0)'	System	07 Sep 2020 03:22:57
	System	07 Sep 2020 03:22:57

US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:48:59

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)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-06T22:22:51', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '9b74aef2-7ace-43a0-a0fc-ea0135c04ecc' User entered 'No (N)'	System	07 Sep 2020 03:22:57
	System	07 Sep 2020 03:22:57

**US3032115**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:48:59**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-06T22:22:53', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '9b74aef2-7ace-43a0-a0fc-ea0135c04ecc' User entered '06 Sep 2020 22:22'	System	07 Sep 2020 03:22:57
	System	07 Sep 2020 03:22:57



**US3032115**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:48:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 15:34:47

US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 15:34:47

US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
Data entry locked.	System	03 Sep 2020 15:34:47
User entered 'Day 5'	System	03 Sep 2020 15:34:47

US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:48:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-08T07:36:35', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '5436da30-65d7-4870-9f65-8ec99e74fc8a' User entered 'None (0)'	System	08 Sep 2020 12:37:05
	System	08 Sep 2020 12:37:05

US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:48:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-08T07:36:37', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '5436da30-65d7-4870-9f65-8ec99e74fc8a' User entered 'None (0)'	System	08 Sep 2020 12:37:05
	System	08 Sep 2020 12:37:05

US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:48:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-08T07:36:39', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '5436da30-65d7-4870-9f65-8ec99e74fc8a' User entered 'None (0)'	System	08 Sep 2020 12:37:05
	System	08 Sep 2020 12:37:05

US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:48:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-08T07:36:42', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '5436da30-65d7-4870-9f65-8ec99e74fc8a' User entered 'None (0)'	System	08 Sep 2020 12:37:05
	System	08 Sep 2020 12:37:05

US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:48:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-08T07:36:48', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '5436da30-65d7-4870-9f65-8ec99e74fc8a' User entered 'None (0)'	System	08 Sep 2020 12:37:05
	System	08 Sep 2020 12:37:05



**US3032115**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:48:59**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-08T07:36:54', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '5436da30-65d7-4870-9f65-8ec99e74fc8a' User entered 'None (0)'	System	08 Sep 2020 12:37:05
	System	08 Sep 2020 12:37:05

US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:48:59

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)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-08T07:36:58', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '5436da30-65d7-4870-9f65-8ec99e74fc8a' User entered 'No (N)'	System	08 Sep 2020 12:37:05
	System	08 Sep 2020 12:37:05

**US3032115**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:48:59**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-08T07:37:00', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '5436da30-65d7-4870-9f65-8ec99e74fc8a' User entered '08 Sep 2020 07:37'	System	08 Sep 2020 12:37:05
	System	08 Sep 2020 12:37:05

US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 15:34:47

US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:48:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 15:34:47

US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
Data entry locked.	System	03 Sep 2020 15:34:47
User entered 'Day 6'	System	03 Sep 2020 15:34:47

US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:48:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-08T18:33:07', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '0878b5aa-0e63-4095-adaf-76829b51ffb7' User entered 'None (0)'	System	08 Sep 2020 23:33:28
	System	08 Sep 2020 23:33:28

US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:48:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-08T18:33:09', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '0878b5aa-0e63-4095-adaf-76829b51ffb7' User entered 'None (0)'	System	08 Sep 2020 23:33:28
	System	08 Sep 2020 23:33:28



US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:48:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-08T18:33:12', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '0878b5aa-0e63-4095-adaf-76829b51ffb7' User entered 'None (0)'	System	08 Sep 2020 23:33:28
	System	08 Sep 2020 23:33:28

US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:48:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-08T18:33:14', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '0878b5aa-0e63-4095-adaf-76829b51ffb7' User entered 'None (0)'	System	08 Sep 2020 23:33:28
	System	08 Sep 2020 23:33:28

**US3032115**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:48:59**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-08T18:33:16', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '0878b5aa-0e63-4095-adaf-76829b51ffb7' User entered 'None (0)'	System	08 Sep 2020 23:33:28
	System	08 Sep 2020 23:33:28

US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:48:59

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-08T18:33:19', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '0878b5aa-0e63-4095-adaf-76829b51ffb7' User entered 'None (0)'	System	08 Sep 2020 23:33:28
	System	08 Sep 2020 23:33:28

US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:48:59

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)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-08T18:33:22', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '0878b5aa-0e63-4095-adaf-76829b51ffb7' User entered 'No (N)'	System	08 Sep 2020 23:33:28
	System	08 Sep 2020 23:33:28

**US3032115**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:48:59**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-08T18:33:25', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '0878b5aa-0e63-4095-adaf-76829b51ffb7' User entered '08 Sep 2020 18:33'	System	08 Sep 2020 23:33:28
	System	08 Sep 2020 23:33:28

US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 15:34:47

**US3032115**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:48:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 15:34:47



US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
Data entry locked.	System	03 Sep 2020 15:34:47
User entered 'Day 7'	System	03 Sep 2020 15:34:47

**US3032115**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:48:59**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-09T18:26:41', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'caaf1ac4-f7f5-4b92-b911-ba65d1139856' User entered 'None (0)'	System	09 Sep 2020 23:27:08
	System	09 Sep 2020 23:27:08

US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:48:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-09T18:26:44', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'caaf1ac4-f7f5-4b92-b911-ba65d1139856' User entered 'None (0)'	System	09 Sep 2020 23:27:08
	System	09 Sep 2020 23:27:08

US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:48:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-09T18:26:47', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'caaf1ac4-f7f5-4b92-b911-ba65d1139856' User entered 'None (0)'	System	09 Sep 2020 23:27:08
	System	09 Sep 2020 23:27:08

US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:48:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-09T18:26:49', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'caaf1ac4-f7f5-4b92-b911-ba65d1139856' User entered 'None (0)'	System	09 Sep 2020 23:27:08
	System	09 Sep 2020 23:27:08

US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:48:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-09T18:26:52', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'caaf1ac4-f7f5-4b92-b911-ba65d1139856' User entered 'None (0)'	System	09 Sep 2020 23:27:08
	System	09 Sep 2020 23:27:08

US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:48:59

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-09T18:26:54', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'caaf1ac4-f7f5-4b92-b911-ba65d1139856' User entered 'None (0)'	System	09 Sep 2020 23:27:08
	System	09 Sep 2020 23:27:08

US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:48:59

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)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-09T18:26:58', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'caaf1ac4-f7f5-4b92-b911-ba65d1139856' User entered 'No (N)'	System	09 Sep 2020 23:27:08
	System	09 Sep 2020 23:27:08



**US3032115**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:48:59**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-09-09T18:27:03', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'caaf1ac4-f7f5-4b92-b911-ba65d1139856' User entered '09 Sep 2020 18:27'	System	09 Sep 2020 23:27:08
	System	09 Sep 2020 23:27:08

US3032115

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:48:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 15:34:47

**US3032115**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:48:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 15:34:47

US3032115

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:29:21
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered 'Yes (Y)'	(b) (4)	
	Samantha Wieseler (b) (4)	10 Sep 2020 18:07:13
	(b) (4)	

US3032115

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:59

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:29:21
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered '10 Sep 2020'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	10 Sep 2020 18:07:13

US3032115

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:29:21
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	10 Sep 2020 18:07:13

US3032115

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:59

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:29:21
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered empty.	(b) (4) Samantha Wieseler (b) (4) (b) (4)	10 Sep 2020 18:07:13

US3032115

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:48:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:29:26
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered 'Yes (Y)'	(b) (4)	
	Samantha Wieseler (b) (4)	10 Sep 2020 18:07:18
	(b) (4)	



**US3032115**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:48:59**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
User entered 'I'	System	10 Sep 2020 18:07:18

US3032115

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:29:30
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:46:49

US3032115

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:29:30
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered '17 Sep 2020'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:46:49

US3032115

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:29:30
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:46:49

US3032115

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:59

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:29:30
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:46:49

US3032115

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:48:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:29:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:47:08

**US3032115**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:48:59**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
User entered 'I'	System	17 Sep 2020 17:47:08

US3032115

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		07 Apr 2021 20:10:28
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:22:03
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Oct 2020 14:33:53



US3032115

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:59

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		07 Apr 2021 20:10:28
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:22:03
User entered '24 Sep 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Oct 2020 14:33:53

US3032115

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		07 Apr 2021 20:10:28
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:22:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Oct 2020 14:33:53

US3032115

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:59

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		07 Apr 2021 20:10:28
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:22:03
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Oct 2020 14:33:53

US3032115

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:48:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		07 Apr 2021 20:10:31
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:22:03
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Oct 2020 14:33:56

**US3032115**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:48:59**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
User entered 'I'	System	08 Oct 2020 14:33:56

US3032115

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:48:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:31:13
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:22:03
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Oct 2020 14:34:06

US3032115

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:48:59

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:31:13
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:22:03
User entered '8 Oct 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Oct 2020 14:34:06

US3032115

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:48:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:31:13
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:22:03
User entered 'Clinic (Clinic)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Oct 2020 14:34:06



**US3032115**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:48:59**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
User entered 'VISIT3'	System	08 Oct 2020 14:34:06

US3032115

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:31:17
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:22:03
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Oct 2020 14:34:49

US3032115

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:31:17
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:22:03
User entered '8 Oct 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Oct 2020 14:34:49

US3032115

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:31:17
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:22:03
User entered '08:00'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Oct 2020 14:34:49

US3032115

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:59

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
User entered '8 Oct 2020 08:00'	System	08 Oct 2020 14:34:49

US3032115

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:31:17
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:22:03
User entered '36.6' C	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Oct 2020 14:34:49

US3032115

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:31:17
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:22:03
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Oct 2020 14:34:49

US3032115

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:31:17
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:22:03
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Oct 2020 14:34:49



US3032115

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:31:17
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:22:03
User entered '64'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Oct 2020 14:34:49

**US3032115**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:48:59**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
User entered 'bpm'	System	08 Oct 2020 14:34:49

US3032115

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:31:17
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:22:03
User entered '16'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Oct 2020 14:34:49

US3032115

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
User entered 'breaths/min'	System	08 Oct 2020 14:34:49

US3032115

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:31:17
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:22:03
User entered '136'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Oct 2020 14:34:49

**US3032115**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:48:59**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
User entered 'mmHg'	System	08 Oct 2020 14:34:49

US3032115

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:31:17
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:22:03
User entered '89'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Oct 2020 14:34:49

US3032115

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
User entered 'mmHg'	System	08 Oct 2020 14:34:49



US3032115

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:59

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19

US3032115

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:59

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19

US3032115

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:48:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:31:37
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:22:03
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Oct 2020 14:35:02

US3032115

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:48:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:31:37
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:22:03
User entered '8 Oct 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Oct 2020 14:35:02

US3032115

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:48:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:32:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:22:03
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Oct 2020 14:35:14

US3032115

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:48:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:32:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:22:03
User entered '8 Oct 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Oct 2020 14:35:14

US3032115

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:48:59

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:32:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:22:03
User entered '08:17'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Oct 2020 14:35:14

US3032115

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:48:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
User entered '8 Oct 2020 08:17'	System	08 Oct 2020 14:35:14



US3032115

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:48:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:32:08
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:22:03
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	08 Oct 2020 14:35:16

**US3032115**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:48:59**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
User entered 'I'	System	08 Oct 2020 14:35:16

US3032115

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
Data entry locked.	System	06 Aug 2020 17:53:24
User entered 'Day 64'	System	06 Aug 2020 17:53:24

US3032115

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

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)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-10-07T15:15:06', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '35fba87f-15f5-4fc8-8929-295b722fdb58'	System	07 Oct 2020 20:15:25
User entered 'No (N)'	System	07 Oct 2020 20:15:25

US3032115

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

Have you been exposed to someone with 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)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-10-07T15:15:17', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '35fba87f-15f5-4fc8-8929-295b722fdb58'	System	07 Oct 2020 20:15:25
User entered 'No (N)'	System	07 Oct 2020 20:15:25

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-10-07T15:15:21', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '35fba87f-15f5-4fc8-8929-295b722fdb58' User entered '07 Oct 2020 15:15:21'	System	07 Oct 2020 20:15:25
	System	07 Oct 2020 20:15:25

US3032115

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
Data entry locked.	System	06 Aug 2020 17:53:24
User entered '06 Oct 2020 00:01'	System	06 Aug 2020 17:53:24

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
Data entry locked.	System	06 Aug 2020 17:53:24
User entered '10 Oct 2020 23:59'	System	06 Aug 2020 17:53:24



US3032115

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
Data entry locked.	System	06 Aug 2020 17:53:24
User entered 'Day 71'	System	06 Aug 2020 17:53:24

US3032115

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

[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)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-10-13T15:30:27', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '41177feb-1a34-45a6-8cd4-d0b9183d67b9' User entered 'No (N)'	System	13 Oct 2020 20:30:35
	System	13 Oct 2020 20:30:35

US3032115

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

Have you been exposed to someone with 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)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-10-13T15:30:30', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '41177feb-1a34-45a6-8cd4-d0b9183d67b9'	System	13 Oct 2020 20:30:35
User entered 'No (N)'	System	13 Oct 2020 20:30:35

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-10-13T15:30:32', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '41177feb-1a34-45a6-8cd4-d0b9183d67b9' User entered '13 Oct 2020 15:30:32'	System	13 Oct 2020 20:30:35
	System	13 Oct 2020 20:30:35

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
Data entry locked.	System	06 Aug 2020 17:53:24
User entered '13 Oct 2020 00:01'	System	06 Aug 2020 17:53:24

US3032115

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
Data entry locked.	System	06 Aug 2020 17:53:24
User entered '17 Oct 2020 23:59'	System	06 Aug 2020 17:53:24

US3032115

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
Data entry locked.	System	06 Aug 2020 17:53:24
User entered 'Day 78'	System	06 Aug 2020 17:53:24

US3032115

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

[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)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-10-20T07:03:43', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '7237bee5-4746-4361-aba3-5f700832e43b' User entered 'No (N)'	System	20 Oct 2020 12:04:12
	System	20 Oct 2020 12:04:12



US3032115

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

Have you been exposed to someone with 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)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-10-20T07:04:03', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '7237bee5-4746-4361-aba3-5f700832e43b' User entered 'No (N)'	System	20 Oct 2020 12:04:12
	System	20 Oct 2020 12:04:12

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-10-20T07:04:10', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '7237bee5-4746-4361-aba3-5f700832e43b' User entered '20 Oct 2020 07:04:10'	System	20 Oct 2020 12:04:12
	System	20 Oct 2020 12:04:12

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
Data entry locked.	System	06 Aug 2020 17:53:24
User entered '20 Oct 2020 00:01'	System	06 Aug 2020 17:53:24

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
Data entry locked.	System	06 Aug 2020 17:53:24
User entered '24 Oct 2020 23:59'	System	06 Aug 2020 17:53:24

US3032115

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
Data entry locked.	System	06 Aug 2020 17:53:24
User entered 'Day 92'	System	06 Aug 2020 17:53:24

US3032115

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

[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)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-11-03T09:22:30', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '96015f75-72c4-4f7b-a280-359d44b0bc42' User entered 'No (N)'	System	03 Nov 2020 15:22:53
	System	03 Nov 2020 15:22:53

US3032115

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

Have you been exposed to someone with 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)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-11-03T09:22:47', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '96015f75-72c4-4f7b-a280-359d44b0bc42'	System	03 Nov 2020 15:22:53
User entered 'No (N)'	System	03 Nov 2020 15:22:53

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-11-03T09:22:51', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '96015f75-72c4-4f7b-a280-359d44b0bc42' User entered '03 Nov 2020 09:22:51'	System	03 Nov 2020 15:22:53
	System	03 Nov 2020 15:22:53



**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
Data entry locked.	System	06 Aug 2020 17:53:24
User entered '03 Nov 2020 00:01'	System	06 Aug 2020 17:53:24

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
Data entry locked.	System	06 Aug 2020 17:53:24
User entered '07 Nov 2020 23:59'	System	06 Aug 2020 17:53:24

US3032115

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
Data entry locked.	System	06 Aug 2020 17:53:24
User entered 'Day 99'	System	06 Aug 2020 17:53:24

US3032115

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

[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)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-11-10T12:09:36', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'eba25dfd-ddc9-4775-a8db-53053bfe8844' User entered 'No (N)'	System	10 Nov 2020 18:09:58
	System	10 Nov 2020 18:09:58

US3032115

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

Have you been exposed to someone with 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)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-11-10T12:09:50', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'eba25dfd-ddc9-4775-a8db-53053bfe8844' User entered 'No (N)'	System	10 Nov 2020 18:09:58
	System	10 Nov 2020 18:09:58

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-11-10T12:09:54', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'eba25dfd-ddc9-4775-a8db-53053bfe8844' User entered '10 Nov 2020 12:09:54'	System	10 Nov 2020 18:09:58
	System	10 Nov 2020 18:09:58

US3032115

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
Data entry locked.	System	06 Aug 2020 17:53:24
User entered '10 Nov 2020 00:01'	System	06 Aug 2020 17:53:24

US3032115

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
Data entry locked.	System	06 Aug 2020 17:53:24
User entered '14 Nov 2020 23:59'	System	06 Aug 2020 17:53:24



US3032115

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
Data entry locked.	System	06 Aug 2020 17:53:24
User entered 'Day 106'	System	06 Aug 2020 17:53:24

US3032115

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

[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)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-11-17T08:10:58', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '7255dc92-1c12-4d5e-bbe7-76a569624029'	System	17 Nov 2020 14:11:18
User entered 'No (N)'	System	17 Nov 2020 14:11:18

US3032115

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

Have you been exposed to someone with 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)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-11-17T08:11:10', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '7255dc92-1c12-4d5e-bbe7-76a569624029'	System	17 Nov 2020 14:11:18
User entered 'No (N)'	System	17 Nov 2020 14:11:18

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-11-17T08:11:14', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '7255dc92-1c12-4d5e-bbe7-76a569624029' User entered '17 Nov 2020 08:11:14'	System	17 Nov 2020 14:11:18
	System	17 Nov 2020 14:11:18

US3032115

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
Data entry locked.	System	06 Aug 2020 17:53:24
User entered '17 Nov 2020 00:01'	System	06 Aug 2020 17:53:24

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:42:55
Data entry locked.	System	06 Aug 2020 17:53:24
User entered '21 Nov 2020 23:59'	System	06 Aug 2020 17:53:24

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 14:42:34

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[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 (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-11-24T09:50:02', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '926ef2e4-ba95-4fdd-babd-b1e3ea8a69ac' User entered 'No (N)'	System	24 Nov 2020 15:50:14



US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

Have you been exposed to someone with 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 (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-11-24T09:50:06', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '926ef2e4-ba95-4fdd-babd-b1e3ea8a69ac' User entered 'No (N)'	System	24 Nov 2020 15:50:14

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-11-24T09:50:10', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '926ef2e4-ba95-4fdd-babd-b1e3ea8a69ac' User entered '24 Nov 2020 09:50:10'	System	24 Nov 2020 15:50:14

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 14:42:34

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[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 (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-11-30T11:43:11', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'f26b3cfb-d847-4c06-a36a-f100f598df54'	System	30 Nov 2020 17:43:21
User entered 'No (N)'	System	30 Nov 2020 17:43:21

US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

Have you been exposed to someone with 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 (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-11-30T11:43:14', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'f26b3cfb-d847-4c06-a36a-f100f598df54'	System	30 Nov 2020 17:43:21
User entered 'No (N)'	System	30 Nov 2020 17:43:21

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-11-30T11:43:16', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'f26b3cfb-d847-4c06-a36a-f100f598df54' User entered '30 Nov 2020 11:43:16'	System	30 Nov 2020 17:43:21



**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 14:42:34

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[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 (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-12-05T08:13:48', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '79c82edc-d1e3-49a9-b49b-dcad582e937e' User entered 'No (N)'	System	05 Dec 2020 14:13:55
	System	05 Dec 2020 14:13:55

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

Have you been exposed to someone with 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 (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-12-05T08:13:50', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '79c82edc-d1e3-49a9-b49b-dcad582e937e' User entered 'No (N)'	System	05 Dec 2020 14:13:55
	System	05 Dec 2020 14:13:55

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-12-05T08:13:53', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '79c82edc-d1e3-49a9-b49b-dcad582e937e' User entered '05 Dec 2020 08:13:53'	System	05 Dec 2020 14:13:55
	System	05 Dec 2020 14:13:55

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 14:42:34



**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 14:42:34

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[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 (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-12-13T13:31:27', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'ae8dfa89-ce08-4507-8fa6-4020bdf1b7ae'	System	13 Dec 2020 19:33:08
User entered 'Yes (Y)'	System	13 Dec 2020 19:33:08

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

Have you been exposed to someone with 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 (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-12-13T13:31:41', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'ae8dfa89-ce08-4507-8fa6-4020bdf1b7ae'	System	13 Dec 2020 19:33:08
User entered 'Yes (Y)'	System	13 Dec 2020 19:33:08

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Please 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 (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-12-13T13:31:51', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'ae8dfa89-ce08-4507-8fa6-4020bdf1b7ae'	System	13 Dec 2020 19:33:08
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	13 Dec 2020 19:33:08

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[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 (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-12-13T13:32:01', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'ae8dfa89-ce08-4507-8fa6-4020bdf1b7ae' User entered 'Yes (Y)'	System	13 Dec 2020 19:33:08

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-12-13T13:32:31', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'ae8dfa89-ce08-4507-8fa6-4020bdf1b7ae' User entered '1'	System	13 Dec 2020 19:33:08

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-12-13T13:32:31', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'ae8dfa89-ce08-4507-8fa6-4020bdf1b7ae' User entered '1'	System	13 Dec 2020 19:33:08

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-12-13T13:32:31', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'ae8dfa89-ce08-4507-8fa6-4020bdf1b7ae' User entered '1'	System	13 Dec 2020 19:33:08



**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-12-13T13:32:31', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'ae8dfa89-ce08-4507-8fa6-4020bdf1b7ae' User entered '1'	System	13 Dec 2020 19:33:08
	System	13 Dec 2020 19:33:08

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-12-13T13:32:31', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'ae8dfa89-ce08-4507-8fa6-4020bdf1b7ae' User entered '1'	System	13 Dec 2020 19:33:08

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-12-13T13:32:31', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'ae8dfa89-ce08-4507-8fa6-4020bdf1b7ae' User entered '1'	System	13 Dec 2020 19:33:08

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-12-13T13:32:31', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'ae8dfa89-ce08-4507-8fa6-4020bdf1b7ae' User entered '1'	System	13 Dec 2020 19:33:08

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-12-13T13:32:31', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'ae8dfa89-ce08-4507-8fa6-4020bdf1b7ae' User entered '1'	System	13 Dec 2020 19:33:08

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-12-13T13:32:31', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'ae8dfa89-ce08-4507-8fa6-4020bdf1b7ae' User entered '1'	System	13 Dec 2020 19:33:08

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-12-13T13:32:31', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'ae8dfa89-ce08-4507-8fa6-4020bdf1b7ae' User entered '1'	System	13 Dec 2020 19:33:08

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-12-13T13:32:31', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'ae8dfa89-ce08-4507-8fa6-4020bdf1b7ae' User entered '1'	System	13 Dec 2020 19:33:08



**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-12-13T13:32:31', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'ae8dfa89-ce08-4507-8fa6-4020bdf1b7ae' User entered '1'	System	13 Dec 2020 19:33:08

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-12-13T13:32:31', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'ae8dfa89-ce08-4507-8fa6-4020bdf1b7ae' User entered '0'	System	13 Dec 2020 19:33:08
	System	13 Dec 2020 19:33:08

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-12-13T13:32:31', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'ae8dfa89-ce08-4507-8fa6-4020bdf1b7ae' User entered '1'	System	13 Dec 2020 19:33:08
	System	13 Dec 2020 19:33:08

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-12-13T13:32:31', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'ae8dfa89-ce08-4507-8fa6-4020bdf1b7ae' User entered '1'	System	13 Dec 2020 19:33:08

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-12-13T13:32:31', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'ae8dfa89-ce08-4507-8fa6-4020bdf1b7ae' User entered '0'	System	13 Dec 2020 19:33:08
	System	13 Dec 2020 19:33:08

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-12-13T13:32:31', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'ae8dfa89-ce08-4507-8fa6-4020bdf1b7ae' User entered '1'	System	13 Dec 2020 19:33:08

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

Please 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 (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-12-13T13:32:38', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'ae8dfa89-ce08-4507-8fa6-4020bdf1b7ae'	System	13 Dec 2020 19:33:08
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	13 Dec 2020 19:33:08

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[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 (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-12-13T13:32:46', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'ae8dfa89-ce08-4507-8fa6-4020bdf1b7ae'	System	13 Dec 2020 19:33:08
User entered 'Yes (Y)'	System	13 Dec 2020 19:33:08



**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Please 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 (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-12-13T13:32:54', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'ae8dfa89-ce08-4507-8fa6-4020bdf1b7ae'	System	13 Dec 2020 19:33:08
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	13 Dec 2020 19:33:08

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-12-13T13:32:58', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'ae8dfa89-ce08-4507-8fa6-4020bdf1b7ae' User entered '13 Dec 2020 13:32:58'	System	13 Dec 2020 19:33:08

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 14:42:34

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[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 (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-12-21T05:48:55', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '13086aa2-21d7-4a8f-a67d-49f1b5d9c7e0'	System	21 Dec 2020 11:49:17
User entered 'No (N)'	System	21 Dec 2020 11:49:17

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Have you been exposed to someone with 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 (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-12-21T05:49:10', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '13086aa2-21d7-4a8f-a67d-49f1b5d9c7e0'	System	21 Dec 2020 11:49:17
User entered 'No (N)'	System	21 Dec 2020 11:49:17

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-12-21T05:49:13', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '13086aa2-21d7-4a8f-a67d-49f1b5d9c7e0' User entered '21 Dec 2020 05:49:13'	System	21 Dec 2020 11:49:17
	System	21 Dec 2020 11:49:17



**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 14:42:34

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[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 (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-12-27T10:52:28', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'da54a567-1fdd-43ec-be85-08a1e8831838'	System	27 Dec 2020 16:53:24
User entered 'Yes (Y)'	System	27 Dec 2020 16:53:24

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Have you been exposed to someone with 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 (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-12-27T10:52:37', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'da54a567-1fdd-43ec-be85-08a1e8831838'	System	27 Dec 2020 16:53:24
User entered 'No (N)'	System	27 Dec 2020 16:53:24

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[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 (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-12-27T10:52:49', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'da54a567-1fdd-43ec-be85-08a1e8831838'	System	27 Dec 2020 16:53:24
User entered 'No (N)'	System	27 Dec 2020 16:53:24

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[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 (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-12-27T10:53:00', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'da54a567-1fdd-43ec-be85-08a1e8831838'	System	27 Dec 2020 16:53:24
User entered 'Yes (Y)'	System	27 Dec 2020 16:53:24

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

Please 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 (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-12-27T10:53:10', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'da54a567-1fdd-43ec-be85-08a1e8831838'	System	27 Dec 2020 16:53:24
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	27 Dec 2020 16:53:24



**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2020-12-27T10:53:15', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'da54a567-1fdd-43ec-be85-08a1e8831838' User entered '27 Dec 2020 10:53:15'	System	27 Dec 2020 16:53:24
	System	27 Dec 2020 16:53:24

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 14:42:34

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[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 (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2021-01-03T20:31:20', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '087ce3fc-b552-4915-8628-ddf34c85900a' User entered 'No (N)'	System	04 Jan 2021 02:31:35

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Have you been exposed to someone with 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 (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2021-01-03T20:31:23', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '087ce3fc-b552-4915-8628-ddf34c85900a' User entered 'No (N)'	System	04 Jan 2021 02:31:35

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2021-01-03T20:31:27', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '087ce3fc-b552-4915-8628-ddf34c85900a' User entered '03 Jan 2021 20:31:27'	System	04 Jan 2021 02:31:35
	System	04 Jan 2021 02:31:35

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 14:42:34



**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 14:42:34

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[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 (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2021-01-10T10:13:34', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'b89802f3-af2c-49a3-bc22-791075e3fa40'	System	10 Jan 2021 16:13:47
User entered 'No (N)'	System	10 Jan 2021 16:13:47

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Have you been exposed to someone with 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 (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2021-01-10T10:13:40', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'b89802f3-af2c-49a3-bc22-791075e3fa40'	System	10 Jan 2021 16:13:47
User entered 'No (N)'	System	10 Jan 2021 16:13:47

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2021-01-10T10:13:44', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'b89802f3-af2c-49a3-bc22-791075e3fa40' User entered '10 Jan 2021 10:13:44'	System	10 Jan 2021 16:13:47
	System	10 Jan 2021 16:13:47

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 14:42:34



**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[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 (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2021-01-16T08:13:17', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '12b260b0-dd92-4541-93da-9e8145462273'	System	16 Jan 2021 14:13:27
User entered 'No (N)'	System	16 Jan 2021 14:13:27

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Have you been exposed to someone with 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 (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2021-01-16T08:13:20', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '12b260b0-dd92-4541-93da-9e8145462273'	System	16 Jan 2021 14:13:27
User entered 'No (N)'	System	16 Jan 2021 14:13:27

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2021-01-16T08:13:23', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '12b260b0-dd92-4541-93da-9e8145462273' User entered '16 Jan 2021 08:13:23'	System	16 Jan 2021 14:13:27
	System	16 Jan 2021 14:13:27

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 14:42:34

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[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 (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2021-01-25T16:23:45', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '257d9c1e-5a0b-4cff-a883-f54ff97a1d83' User entered 'No (N)'	System	25 Jan 2021 22:23:55
	System	25 Jan 2021 22:23:55

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

Have you been exposed to someone with 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 (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2021-01-25T16:23:48', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '257d9c1e-5a0b-4cff-a883-f54ff97a1d83'	System	25 Jan 2021 22:23:55
User entered 'No (N)'	System	25 Jan 2021 22:23:55



**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2021-01-25T16:23:51', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '257d9c1e-5a0b-4cff-a883-f54ff97a1d83' User entered '25 Jan 2021 16:23:51'	System	25 Jan 2021 22:23:55
	System	25 Jan 2021 22:23:55

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 14:42:34

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[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 (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2021-01-30T22:41:38', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '7f294269-1abb-4264-8361-d30c5cdc853e'	System	31 Jan 2021 04:41:47
User entered 'No (N)'	System	31 Jan 2021 04:41:47

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

Have you been exposed to someone with 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 (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2021-01-30T22:41:40', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '7f294269-1abb-4264-8361-d30c5cdc853e'	System	31 Jan 2021 04:41:47
User entered 'No (N)'	System	31 Jan 2021 04:41:47

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2021-01-30T22:41:42', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '7f294269-1abb-4264-8361-d30c5cdc853e' User entered '30 Jan 2021 22:41:42'	System	31 Jan 2021 04:41:47
	System	31 Jan 2021 04:41:47

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 14:42:34



**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 14:42:34

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[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 (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2021-02-07T05:51:20', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'f57801ba-b09f-4d30-a95d-a62d705b1c09'	System	07 Feb 2021 11:51:29
User entered 'No (N)'	System	07 Feb 2021 11:51:29

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

Have you been exposed to someone with 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 (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2021-02-07T05:51:22', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'f57801ba-b09f-4d30-a95d-a62d705b1c09'	System	07 Feb 2021 11:51:29
User entered 'No (N)'	System	07 Feb 2021 11:51:29

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2021-02-07T05:51:25', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'f57801ba-b09f-4d30-a95d-a62d705b1c09'	System	07 Feb 2021 11:51:29
User entered '07 Feb 2021 05:51:25'	System	07 Feb 2021 11:51:29

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 14:42:34



**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[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 (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2021-02-14T08:44:46', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'b4d0e13e-a3e2-45f0-9294-e83a6514e161' User entered 'No (N)'	System	14 Feb 2021 14:44:57
	System	14 Feb 2021 14:44:57

US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

Have you been exposed to someone with 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 (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2021-02-14T08:44:51', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'b4d0e13e-a3e2-45f0-9294-e83a6514e161' User entered 'No (N)'	System	14 Feb 2021 14:44:57
	System	14 Feb 2021 14:44:57

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2021-02-14T08:44:54', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'b4d0e13e-a3e2-45f0-9294-e83a6514e161' User entered '14 Feb 2021 08:44:54'	System	14 Feb 2021 14:44:57
	System	14 Feb 2021 14:44:57

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 14:42:34

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[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 (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2021-02-20T05:56:00', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '1ee70fca-95b0-4d98-951e-db2dfb1091f2'	System	20 Feb 2021 11:56:23
User entered 'No (N)'	System	20 Feb 2021 11:56:23

US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

Have you been exposed to someone with 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 (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2021-02-20T05:56:13', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '1ee70fca-95b0-4d98-951e-db2dfb1091f2'	System	20 Feb 2021 11:56:23
User entered 'No (N)'	System	20 Feb 2021 11:56:23



**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2021-02-20T05:56:18', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '1ee70fca-95b0-4d98-951e-db2dfb1091f2'	System	20 Feb 2021 11:56:23
User entered '20 Feb 2021 05:56:18'	System	20 Feb 2021 11:56:23

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 14:42:34

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[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 (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2021-02-27T10:45:39-06:00', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '23ad9e0f-b0d1-4dc8-ab33-98c776e86e60'	System	27 Feb 2021 16:45:50
User entered 'No (N)'	System	27 Feb 2021 16:45:50

US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

Have you been exposed to someone with 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 (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2021-02-27T10:45:41-06:00', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '23ad9e0f-b0d1-4dc8-ab33-98c776e86e60'	System	27 Feb 2021 16:45:50
User entered 'No (N)'	System	27 Feb 2021 16:45:50

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2021-02-27T10:45:46-06:00', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '23ad9e0f-b0d1-4dc8-ab33-98c776e86e60' User entered '27 Feb 2021 16:45:46'	System	27 Feb 2021 16:45:50
	System	27 Feb 2021 16:45:50

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 14:42:34



**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 14:42:34

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[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 (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2021-03-07T20:42:05-06:00', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'db893d02-46cc-4371-a210-7f5f768cb5dc' User entered 'No (N)'	System	08 Mar 2021 02:43:08

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Have you been exposed to someone with 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 (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2021-03-07T20:42:09-06:00', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'db893d02-46cc-4371-a210-7f5f768cb5dc'	System	08 Mar 2021 02:43:08
User entered 'No (N)'	System	08 Mar 2021 02:43:08

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2021-03-07T20:42:11-06:00', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'db893d02-46cc-4371-a210-7f5f768cb5dc' User entered '07 Mar 2021 20:42:11'	System	08 Mar 2021 02:43:08
	System	08 Mar 2021 02:43:08

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 14:42:34



**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[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 (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2021-03-14T17:42:14-05:00', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '659fc081-ffb6-434d-994f-1103d4f10dad'	System	14 Mar 2021 22:42:23
User entered 'No (N)'	System	14 Mar 2021 22:42:23

US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

Have you been exposed to someone with 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 (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2021-03-14T17:42:16-05:00', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '659fc081-ffb4-434d-994f-1103d4f10dad'	System	14 Mar 2021 22:42:23
User entered 'No (N)'	System	14 Mar 2021 22:42:23

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2021-03-14T17:42:19-05:00', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '659fc081-ffb6-434d-994f-1103d4f10dad' User entered '14 Mar 2021 17:42:19'	System	14 Mar 2021 22:42:23
	System	14 Mar 2021 22:42:23

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 14:42:34

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[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 (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2021-03-20T08:54:48-05:00', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '07e602c1-b3cd-4eec-9a31-e858c2d63c8d' User entered 'No (N)'	System	20 Mar 2021 13:54:55
	System	20 Mar 2021 13:54:55

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Have you been exposed to someone with 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 (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2021-03-20T08:54:51-05:00', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '07e602c1-b3cd-4eec-9a31-e858c2d63c8d' User entered 'No (N)'	System	20 Mar 2021 13:54:55
	System	20 Mar 2021 13:54:55



**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2021-03-20T08:54:53-05:00', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '07e602c1-b3cd-4eec-9a31-e858c2d63c8d' User entered '20 Mar 2021 08:54:53'	System	20 Mar 2021 13:54:55
	System	20 Mar 2021 13:54:55

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 14:42:34

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[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 (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2021-03-27T09:04:02-05:00', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'baae3eb9-43a8-417b-9413-d1880d406aed'	System	27 Mar 2021 14:04:11
User entered 'No (N)'	System	27 Mar 2021 14:04:11

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

Have you been exposed to someone with 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 (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2021-03-27T09:04:04-05:00', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'baae3eb9-43a8-417b-9413-d1880d406aed'	System	27 Mar 2021 14:04:11
User entered 'No (N)'	System	27 Mar 2021 14:04:11

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2021-03-27T09:04:07-05:00', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'baae3eb9-43a8-417b-9413-d1880d406aed' User entered '27 Mar 2021 09:04:07'	System	27 Mar 2021 14:04:11
	System	27 Mar 2021 14:04:11

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 14:42:34



**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 14:42:34

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[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 (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2021-04-03T09:59:25-05:00', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '8242a9e3-c1b9-4270-b3a6-8dd8e421da9a'	System	03 Apr 2021 14:59:45
User entered 'No (N)'	System	03 Apr 2021 14:59:45

US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

Have you been exposed to someone with 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 (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2021-04-03T09:59:38-05:00', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '8242a9e3-c1b9-4270-b3a6-8dd8e421da9a'	System	03 Apr 2021 14:59:45
User entered 'No (N)'	System	03 Apr 2021 14:59:45

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2021-04-03T09:59:42-05:00', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '8242a9e3-c1b9-4270-b3a6-8dd8e421da9a'	System	03 Apr 2021 14:59:45
User entered '03 Apr 2021 09:59:42'	System	03 Apr 2021 14:59:45

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 14:42:34



**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[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 (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2021-04-10T14:43:02-05:00', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'd0bd1562-1e98-4085-aad4-cfd888d90da7'	System	10 Apr 2021 19:43:10
User entered 'No (N)'	System	10 Apr 2021 19:43:10

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

Have you been exposed to someone with 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 (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2021-04-10T14:43:04-05:00', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'd0bd1562-1e98-4085-aad4-cfd888d90da7'	System	10 Apr 2021 19:43:10
User entered 'No (N)'	System	10 Apr 2021 19:43:10

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2021-04-10T14:43:06-05:00', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'd0bd1562-1e98-4085-aad4-cfd888d90da7'	System	10 Apr 2021 19:43:10
User entered '10 Apr 2021 14:43:06'	System	10 Apr 2021 19:43:10

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 14:42:34

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[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 (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2021-04-17T10:15:25-05:00', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'b16b56a0-d3ca-43c5-9fee-c4f2d9768146'	System	17 Apr 2021 15:15:40
User entered 'No (N)'	System	17 Apr 2021 15:15:40

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Have you been exposed to someone with 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 (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2021-04-17T10:15:27-05:00', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'b16b56a0-d3ca-43c5-9fee-c4f2d9768146'	System	17 Apr 2021 15:15:40
User entered 'No (N)'	System	17 Apr 2021 15:15:40



**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2021-04-17T10:15:37-05:00', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'b16b56a0-d3ca-43c5-9fee-c4f2d9768146'	System	17 Apr 2021 15:15:40
User entered '17 Apr 2021 10:15:37'	System	17 Apr 2021 15:15:40

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 14:42:34

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[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 (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2021-04-25T20:03:17-05:00', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '21509cc0-17e6-47d7-a389-c8284ea45c25'	System	26 Apr 2021 01:08:42
User entered 'Yes (Y)'	System	26 Apr 2021 01:08:42

US3032115

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:48:59

Have you been exposed to someone with 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 (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2021-04-25T20:03:23-05:00', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '21509cc0-17e6-47d7-a389-c8284ea45c25' User entered 'No (N)'	System	26 Apr 2021 01:08:42
	System	26 Apr 2021 01:08:42

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[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 (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2021-04-25T20:03:34-05:00', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '21509cc0-17e6-47d7-a389-c8284ea45c25' User entered 'No (N)'	System	26 Apr 2021 01:08:42
	System	26 Apr 2021 01:08:42

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[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 (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2021-04-25T20:03:42-05:00', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '21509cc0-17e6-47d7-a389-c8284ea45c25'	System	26 Apr 2021 01:08:42
User entered 'Yes (Y)'	System	26 Apr 2021 01:08:42



**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Please 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 (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2021-04-25T20:03:52-05:00', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '21509cc0-17e6-47d7-a389-c8284ea45c25'	System	26 Apr 2021 01:08:42
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	26 Apr 2021 01:08:42

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2021-04-25T20:03:55-05:00', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: '21509cc0-17e6-47d7-a389-c8284ea45c25'	System	26 Apr 2021 01:08:42
User entered '25 Apr 2021 20:03:55'	System	26 Apr 2021 01:08:42

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 14:42:34

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[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 (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2021-05-02T07:19:30-05:00', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'e06f6d63-b6af-4401-bc6d-3064ae2f9949'	System	02 May 2021 12:19:38
User entered 'No (N)'	System	02 May 2021 12:19:38

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

Have you been exposed to someone with 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 (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2021-05-02T07:19:32-05:00', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'e06f6d63-b6af-4401-bc6d-3064ae2f9949'	System	02 May 2021 12:19:38
User entered 'No (N)'	System	02 May 2021 12:19:38

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2021-05-02T07:19:35-05:00', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'e06f6d63-b6af-4401-bc6d-3064ae2f9949'	System	02 May 2021 12:19:38
User entered '02 May 2021 07:19:35'	System	02 May 2021 12:19:38



**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 14:42:34



**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 14:42:34



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 14:42:34



**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 14:42:34



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 14:42:34



**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 14:42:34



**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 14:42:34



**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 14:42:34



**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 14:42:34



**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 14:42:34



**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 14:42:34



**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 14:42:34



**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 14:42:34



**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 14:42:34



**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 14:42:34



**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 14:42:34



**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 14:42:34



**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 14:42:34



**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 14:42:34



**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 14:42:34



**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 14:42:34



**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 14:42:34



**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 14:42:34



**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 14:42:34



**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 14:42:34



**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 14:42:34



**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 14:42:34



**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 14:42:34



**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 14:42:34

**US3032115**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:48:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:42:34
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 14:42:34

US3032115

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 14:48:59

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2021-02-27T10:45:56-06:00', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'f25142c0-4ceb-4759-8a0d-e4960cef8ad9'	System	27 Feb 2021 16:46:07
User entered 'No (N)'	System	27 Feb 2021 16:46:07

**US3032115**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 14:48:59**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:14:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (01F1477A-60BF-45CF-9445-47485C43FAD3)', Time: '2021-02-27T10:46:04-06:00', User OID: 'PatientReportedOutcome (US3032115)', ODM File OID: 'f25142c0-4ceb-4759-8a0d-e4960cef8ad9' User entered '27 Feb 2021 16:46:04'	System	27 Feb 2021 16:46:07
	System	27 Feb 2021 16:46:07

**US3032115**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:48:59**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:32:35
User signature succeeded.	Keith Vrbicky (b) (4)	28 Oct 2020 15:25:04
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Oct 2020 13:42:30

US3032115

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:59

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:32:35
User signature succeeded.	Keith Vrbicky (b) (4)	28 Oct 2020 15:25:04
User entered '27 Oct 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Oct 2020 13:42:30

US3032115

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:32:35
User signature succeeded.	Keith Vrbicky (b) (4)	28 Oct 2020 15:25:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Oct 2020 13:42:30



US3032115

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:59

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:32:35
User signature succeeded.	Keith Vrbicky (b) (4)	28 Oct 2020 15:25:04
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Oct 2020 13:42:30

US3032115

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:48:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
DataPoint Verified.		17 Dec 2020 20:32:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Oct 2020 15:25:04
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Oct 2020 13:42:56

**US3032115**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:48:59**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:00:19
User entered 'I'	System	28 Oct 2020 13:42:56

US3032115

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:37
DataPoint Verified.		07 Apr 2021 20:12:11
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	System	29 Dec 2020 16:59:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Dec 2020 16:59:26
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 16:59:26
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Dec 2020 16:59:07
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 16:59:07

US3032115

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:59

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:37
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:20:03
User closed query 'Per the source this call was conducted on 20NOV20 please refer to the source and update.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	13 Apr 2021 14:17:11
DataPoint Verified.		13 Apr 2021 14:16:58
Query 'Per the source this call was conducted on 20NOV20 please refer to the source and update.' answered with 'updated' (Site from CRA).	Samantha Wieseler (b) (4)	13 Apr 2021 13:43:43
Signature has been broken.	(b) (4)	
	Samantha Wieseler (b) (4)	13 Apr 2021 13:43:14
User entered '20 Nov 2020' reason for change: Data Entry Error	(b) (4)	
	Samantha Wieseler (b) (4)	13 Apr 2021 13:43:14
User opened query 'Per the source this call was conducted on 20NOV20 please refer to the source and update.' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 20:12:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
User entered '18 Nov 2020'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 16:59:07

US3032115

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:37
DataPoint Verified.		07 Apr 2021 20:12:12
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 16:59:07

US3032115

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:59

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:37
DataPoint Verified.		07 Apr 2021 20:12:15
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 16:59:07

US3032115

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:48:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:37
DataPoint Verified.		07 Apr 2021 20:12:20
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 16:59:14



**US3032115**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:48:59**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:37
User entered 'I'	System	29 Dec 2020 16:59:14

US3032115

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:37
DataPoint Verified.		07 Apr 2021 20:14:35
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 17:00:26

US3032115

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:59

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:37
DataPoint Verified.		07 Apr 2021 20:14:35
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
User entered '29 Dec 2020'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 17:00:26

US3032115

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:37
DataPoint Verified.		07 Apr 2021 20:14:35
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 17:00:26

US3032115

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:59

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:37
DataPoint Verified.		07 Apr 2021 20:14:35
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 17:00:26

US3032115

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:48:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:37
DataPoint Verified.		07 Apr 2021 20:14:41
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 17:00:31

**US3032115**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:48:59**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:37
User entered 'I'	System	29 Dec 2020 17:00:31

**US3032115**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:48:59**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:37
DataPoint Verified.		07 Apr 2021 20:15:14
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:39:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 22:58:39



US3032115

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:59

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:37
DataPoint Verified.		07 Apr 2021 20:15:14
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:39:23
User entered '03 Feb 2021'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 22:58:39

US3032115

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:37
DataPoint Verified.		07 Apr 2021 20:15:14
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:39:23
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 22:58:39

US3032115

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:59

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:37
DataPoint Verified.		07 Apr 2021 20:15:14
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:39:23
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 22:58:39

US3032115

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:48:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:37
DataPoint Verified.		07 Apr 2021 20:15:20
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:39:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 22:58:44

**US3032115**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:48:59**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:37
User entered 'I'	System	04 Feb 2021 22:58:44

US3032115

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:48:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		07 Apr 2021 20:18:38
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:21:18
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	05 Mar 2021 20:14:47

US3032115

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:48:59

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		07 Apr 2021 20:18:38
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:21:18
User entered '04 Mar 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	05 Mar 2021 20:14:47

US3032115

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:48:59

[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 02:13:03
DataPoint Verified.		07 Apr 2021 20:18:38
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:21:18
User entered 'Clinic (Clinic)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	05 Mar 2021 20:14:47



**US3032115**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:48:59**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered 'VISIT4'	System	05 Mar 2021 20:14:47

US3032115

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		07 Apr 2021 20:19:00
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:21
User entered 'No (N)'	(b) (4)	
	Samantha Wieseler (b) (4)	29 Mar 2021 21:09:10
	(b) (4)	

US3032115

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		07 Apr 2021 20:19:00
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:21
User entered empty.	(b) (4)	
	Samantha Wieseler (b) (4)	29 Mar 2021 21:09:10
	(b) (4)	

US3032115

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:59

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		07 Apr 2021 20:19:00
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:21
User entered empty.	(b) (4)	
	Samantha Wieseler (b) (4)	29 Mar 2021 21:09:10
	(b) (4)	

US3032115

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:59

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered empty.	System	29 Mar 2021 21:09:10

US3032115

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		07 Apr 2021 20:19:00
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:21
User entered empty.	(b) (4)	
	Samantha Wieseler (b) (4)	29 Mar 2021 21:09:10
	(b) (4)	

US3032115

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		07 Apr 2021 20:19:00
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:21
User entered empty.	(b) (4)	
	Samantha Wieseler (b) (4)	29 Mar 2021 21:09:10
	(b) (4)	

US3032115

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		07 Apr 2021 20:19:00
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:21
User entered empty.	(b) (4)	
	Samantha Wieseler (b) (4)	29 Mar 2021 21:09:10
	(b) (4)	



US3032115

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		07 Apr 2021 20:19:00
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:21
User entered empty.	(b) (4)	
	Samantha Wieseler (b) (4)	29 Mar 2021 21:09:10
	(b) (4)	

**US3032115**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:48:59**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered empty.	System	29 Mar 2021 21:09:10

US3032115

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		07 Apr 2021 20:19:00
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:21
User entered empty.	(b) (4)	
	Samantha Wieseler (b) (4)	29 Mar 2021 21:09:10
	(b) (4)	

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Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered empty.	System	29 Mar 2021 21:09:10

US3032115

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		07 Apr 2021 20:19:00
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:21
User entered empty.	(b) (4)	
	Samantha Wieseler (b) (4)	29 Mar 2021 21:09:10
	(b) (4)	

US3032115

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered empty.	System	29 Mar 2021 21:09:10

US3032115

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		07 Apr 2021 20:19:00
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:21
User entered empty.	(b) (4)	
	Samantha Wieseler (b) (4)	29 Mar 2021 21:09:10
	(b) (4)	

US3032115

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered empty.	System	29 Mar 2021 21:09:10



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Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:59

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03

US3032115

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:59

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03

US3032115

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:48:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		07 Apr 2021 20:19:03
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:21:18
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	05 Mar 2021 20:15:36

US3032115

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:48:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		07 Apr 2021 20:19:03
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:21:18
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	05 Mar 2021 20:15:36

US3032115

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:48:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		07 Apr 2021 20:19:10
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:21:18
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	05 Mar 2021 20:15:53

US3032115

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:48:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		07 Apr 2021 20:19:10
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:21:18
User entered '4 Mar 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	05 Mar 2021 20:15:53

US3032115

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:48:59

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		07 Apr 2021 20:19:10
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:21:18
User entered '10:48'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	05 Mar 2021 20:15:53

**US3032115**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:48:59**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered '4 Mar 2021 10:48'	System	05 Mar 2021 20:15:53



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Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:48:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
DataPoint Verified.		07 Apr 2021 20:19:18
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:21:18
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	05 Mar 2021 20:15:56

**US3032115**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:48:59**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:13:03
User entered 'I'	System	05 Mar 2021 20:15:56

**US3032115**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:48:59**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	19 Apr 2021 15:26:28
	(b) (4)	
User entered 'Yes (Y)'	Samantha Wieseler (b) (4)	16 Apr 2021 14:29:15
	(b) (4)	

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Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:59

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	19 Apr 2021 15:26:28
	(b) (4)	
User entered '01 Apr 2021'	Samantha Wieseler (b) (4)	16 Apr 2021 14:29:15
	(b) (4)	

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Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	19 Apr 2021 15:26:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Samantha Wieseler (b) (4)	16 Apr 2021 14:29:15

US3032115

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:48:59

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	19 Apr 2021 15:26:28
	(b) (4)	
User entered empty.	Samantha Wieseler (b) (4)	16 Apr 2021 14:29:15
	(b) (4)	

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Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:48:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	19 Apr 2021 15:26:28
	(b) (4)	
User entered 'Yes (Y)'	Samantha Wieseler (b) (4)	16 Apr 2021 14:29:18
	(b) (4)	

**US3032115**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:48:59**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Apr 2021 14:29:18



US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:48:59

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:16
DataPoint Verified.		17 Dec 2020 20:33:16
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered '8 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:14:45

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:48:59

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:16
DataPoint Verified.		17 Dec 2020 20:33:16
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered '11:15'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:14:45

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:48:59

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:16
User entered '8 Dec 2020 11:15'	System	09 Dec 2020 17:14:45

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:48:59

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:16
DataPoint Verified.		17 Dec 2020 20:33:16
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:14:45

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:48:59

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:16
DataPoint Verified.		17 Dec 2020 20:33:16
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:14:45

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:48:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered 'Day 1 (Day 1)'	(b) (4) Kelsey Kelley (b) (4)	09 Dec 2020 17:16:08

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:48:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered '5 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:16:08

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:48:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered 'l'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:16:08



US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:48:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:16:08

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:48:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
User entered empty.	System	09 Dec 2020 17:16:08

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:48:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:16:08

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:48:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:16:08

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:48:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:16:08

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:48:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:16:08

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:48:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:16:08

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:48:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:16:08



US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:48:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:16:08

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:48:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:16:08

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:48:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:16:08

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:48:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:16:08

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:48:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:16:08

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:48:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:16:08

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:48:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:16:08

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:48:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:16:08



US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:48:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:16:08

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:48:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:16:08

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:48:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:16:08

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:48:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered 'Day 2 (Day 2)'	(b) (4) Kelsey Kelley (b) (4)	09 Dec 2020 17:16:25
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:48:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered '6 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:16:25

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:48:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered 'l'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:16:25

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:48:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:16:25

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:48:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
User entered empty.	System	09 Dec 2020 17:16:25



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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:48:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:16:25

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:48:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:16:25

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:48:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:16:25

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:48:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:16:25

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:48:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:16:25

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:48:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:16:25

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:48:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:16:25

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:48:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:16:25



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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:48:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:16:25

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:48:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:16:25

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:48:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:16:25

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:48:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:16:25

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:48:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:16:25

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:48:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:16:25

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:48:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:16:25

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:48:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:16:25



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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:48:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:16:25

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:48:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered 'Day 3 (Day 3)'	(b) (4) Kelsey Kelley (b) (4)	09 Dec 2020 17:16:32

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:48:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Dec 2020 17:16:41
User entered '7 Dec 2020' reason for change: Data Entry Error	System	09 Dec 2020 17:16:41
User opened query 'Data is required. Please complete.' (Site from System).	Kelsey Kelley (b) (4)	09 Dec 2020 17:16:41
User entered empty.	(b) (4)	
	System	09 Dec 2020 17:16:32
	Kelsey Kelley (b) (4)	09 Dec 2020 17:16:32
	(b) (4)	

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:48:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered 'l'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:16:32

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:48:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:16:32

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:48:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
User entered empty.	System	09 Dec 2020 17:16:32

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:48:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:16:32

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:48:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:16:32



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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:48:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:16:32

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:48:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:16:32

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:48:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:16:32

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:48:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:16:32

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:48:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:16:32

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (3)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:16:32

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:48:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:16:32

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (3)

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:16:32



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Folder: Covid-19 Assessment 08 Dec 2020

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:16:32

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:48:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:16:32

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (3)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:16:32

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:48:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:16:32

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:48:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:16:32

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:48:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:16:32

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:48:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:16:32

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:48:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered 'Day 4 (Day 4)'	(b) (4) Kelsey Kelley (b) (4)	09 Dec 2020 17:17:18



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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (4)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered '8 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:17:18

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:48:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:17:18

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:48:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered missing code ND - Not Done.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:17:18

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:48:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
User entered '%'	System	09 Dec 2020 17:17:18

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:48:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered missing code ND - Not Done.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:17:18

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:48:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:17:18

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:48:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:17:18

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:48:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered 'Mild (Mild)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:17:18



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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:48:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:17:18

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:48:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:17:18

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:48:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:17:18

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:48:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:17:18

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:48:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered 'Severe (Severe)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:17:18

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:48:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered 'Severe (Severe)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:17:18

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:48:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered 'Severe (Severe)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:17:18

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:48:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:17:18



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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (4)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered 'Severe (Severe)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:17:18

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (4)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:17:18

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:48:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:17:18

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:48:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered 'Severe (Severe)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:17:18

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:48:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:17:18

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (5)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered 'Day 5 (Day 5)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:18:19

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (5)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered '9 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:18:19

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:48:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:18:19



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Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:48:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered '98'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:18:19

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:48:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
User entered '%'	System	09 Dec 2020 17:18:19

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:48:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered '36.3' C	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:18:19

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:48:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:18:19

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:48:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered 'Severe (Severe)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:18:19

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:48:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:18:19

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:48:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:18:19

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:48:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:18:19



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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:48:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:18:19

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:48:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:18:19

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:48:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered 'Severe (Severe)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:18:19

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:48:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered 'Severe (Severe)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:18:19

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:48:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:18:19

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:48:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered 'Mild (Mild)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:18:19

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:48:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:18:19

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (5)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:18:19



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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:48:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:18:19

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:48:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:18:19

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:48:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:18:19

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:48:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'Day 6 (Day 6)'	(b) (4) Kelsey Kelley (b) (4)	11 Dec 2020 20:33:43

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:48:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered '10 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 20:33:43

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:48:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 20:33:43

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:48:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered '96'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 20:33:43

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:48:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
User entered '%'	System	11 Dec 2020 20:33:43



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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:48:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered '101.3' F	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 20:33:43

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:48:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 20:33:43

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:48:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 20:33:43

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:48:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 20:33:43

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:48:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 20:33:43

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:48:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'Severe (Severe)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 20:33:43

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:48:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 20:33:43

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:48:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 20:33:43



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Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:48:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 20:33:43

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:48:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 20:33:43

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (6)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 20:33:43

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:48:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'Mild (Mild)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 20:33:43

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:48:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'Mild (Mild)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 20:33:43

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:48:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 20:33:43

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:48:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 20:33:43

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:48:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 20:33:43



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Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:48:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 20:33:43

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Form: Symptom Log (7)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'Day 7 (Day 7)'	(b) (4) Kelsey Kelley (b) (4)	11 Dec 2020 20:34:50

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered '11 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 20:34:50

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Form: Symptom Log (7)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 20:34:50

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:48:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered '95'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 20:34:50

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (7)

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
User entered '%'	System	11 Dec 2020 20:34:50

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Form: Symptom Log (7)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered '99.0' F	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 20:34:50

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:48:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'Mild (Mild)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 20:34:50



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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:48:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 20:34:50

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:48:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 20:34:50

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:48:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 20:34:50

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:48:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 20:34:50

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:48:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 20:34:50

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:48:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 20:34:50

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:48:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 20:34:50

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:48:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 20:34:50



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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 20:34:50

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:48:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'Mild (Mild)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 20:34:50

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:48:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'Mild (Mild)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 20:34:50

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:48:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 20:34:50

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:48:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 20:34:50

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:48:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 20:34:50

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:48:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 20:34:50

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'Day 8 (Day 8)'	(b) (4) Kelsey Kelley (b) (4)	16 Dec 2020 16:28:20



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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered '12 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Dec 2020 16:28:20

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:48:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Dec 2020 16:28:20

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:48:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered '96'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Dec 2020 16:28:20

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:48:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
User entered '%'	System	16 Dec 2020 16:28:20

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:48:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered '98.2' F	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Dec 2020 16:28:20

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:48:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'Mild (Mild)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Dec 2020 16:28:20

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:48:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Dec 2020 16:28:20

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:48:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Dec 2020 16:28:20



US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:48:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Dec 2020 16:28:20

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:48:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Dec 2020 16:28:20

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:48:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Dec 2020 16:28:20

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:48:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Dec 2020 16:28:20

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:48:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Dec 2020 16:28:20

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:48:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Dec 2020 16:28:20

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:48:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Dec 2020 16:28:20

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:48:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'Mild (Mild)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Dec 2020 16:28:20



US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:48:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'Mild (Mild)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Dec 2020 16:28:20

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:48:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Dec 2020 16:28:20

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:48:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Dec 2020 16:28:20

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:48:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Dec 2020 16:28:20

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:48:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Dec 2020 16:28:20

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:48:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'Day 9 (Day 9)'	(b) (4) Kelsey Kelley (b) (4)	16 Dec 2020 16:29:20

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:48:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered '13 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Dec 2020 16:29:20

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:48:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Dec 2020 16:29:20



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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:48:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered '97'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Dec 2020 16:29:20

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:48:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
User entered '%'	System	16 Dec 2020 16:29:20

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:48:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered '97.8' F	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Dec 2020 16:29:20

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:48:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Dec 2020 16:29:20

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:48:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Dec 2020 16:29:20

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:48:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Dec 2020 16:29:20

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:48:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Dec 2020 16:29:20

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:48:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Dec 2020 16:29:20



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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:48:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Dec 2020 16:29:20

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:48:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Dec 2020 16:29:20

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:48:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Dec 2020 16:29:20

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:48:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Dec 2020 16:29:20

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:48:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Dec 2020 16:29:20

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:48:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Dec 2020 16:29:20

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:48:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'Mild (Mild)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Dec 2020 16:29:20

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:48:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Dec 2020 16:29:20



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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:48:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Dec 2020 16:29:20

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:48:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'Mild (Mild)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Dec 2020 16:29:20

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:48:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'Mild (Mild)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Dec 2020 16:29:20

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:48:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'Day 10 (Day 10)'	(b) (4) Kelsey Kelley (b) (4)	16 Dec 2020 16:31:02

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (10)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered '14 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Dec 2020 16:31:02

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (10)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Dec 2020 16:31:02

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:48:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered '99'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Dec 2020 16:31:02

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (10)

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
User entered '%'	System	16 Dec 2020 16:31:02



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Form: Symptom Log (10)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered '97.9' F	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Dec 2020 16:31:02

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:48:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Dec 2020 16:31:02

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:48:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Dec 2020 16:31:02

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:48:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Dec 2020 16:31:02

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:48:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Dec 2020 16:31:02

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:48:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Dec 2020 16:31:02

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:48:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Dec 2020 16:31:02

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:48:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Dec 2020 16:31:02



US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:48:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'Mild (Mild)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Dec 2020 16:31:02

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:48:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Dec 2020 16:31:02

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:48:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Dec 2020 16:31:02

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:48:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Dec 2020 16:31:02

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:48:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'Mild (Mild)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Dec 2020 16:31:02

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:48:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Dec 2020 16:31:02

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:48:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Dec 2020 16:31:02

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:48:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Dec 2020 16:31:02



US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:48:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:21
DataPoint Verified.		17 Dec 2020 20:52:32
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Dec 2020 16:31:02

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:48:59

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:27
DataPoint Verified.		17 Dec 2020 20:58:23
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered '9 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:19:00

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:48:59

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:27
DataPoint Verified.		17 Dec 2020 20:58:23
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:19:00

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:48:59

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:27
DataPoint Verified.		17 Dec 2020 20:58:23
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:19:00

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:48:59

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:27
DataPoint Verified.		17 Dec 2020 20:58:23
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered '9 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:19:00

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:48:59

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:27
DataPoint Verified.		17 Dec 2020 20:58:23
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:19:00

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:48:59

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:27
DataPoint Verified.		17 Dec 2020 20:58:23
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:19:00

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Folder: Covid-19 Assessment 08 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:48:59

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	8 Apr 2021 22:16:27
DataPoint Verified.		7 Dec 2020 20:58:23
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:19:00



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Folder: Covid-19 Assessment 08 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:48:59

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:27
DataPoint Verified.		17 Dec 2020 20:58:23
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:19:00

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Folder: Covid-19 Assessment 08 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:48:59

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:27
DataPoint Verified.		17 Dec 2020 20:58:23
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:19:00

US3032115

Folder: Covid-19 Assessment 08 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:48:59

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:27
User entered '0'	System	09 Dec 2020 17:19:00

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Folder: Covid-19 Assessment 08 Dec 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 14:48:59

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:16:33
DataPoint Verified.		17 Dec 2020 20:58:29
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:14:49

US3032115

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 14:48:59

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:51:52
User closed query 'Per GCL Lab Reconciliation: Saliva : Sample dated 15DEC2020 is reported under Illness Visits 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).		04 Jan 2021 18:44:34
Query 'Per GCL Lab Reconciliation: Saliva : Sample dated 15DEC2020 is reported under Illness Visits 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.	Linden DeBoer (b) (4) (b) (4)	04 Jan 2021 14:40:30
' answered with 'data updated' (Site from DM).		
User opened query 'Per GCL Lab Reconciliation: Saliva : Sample dated 15DEC2020 is reported under Illness Visits 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)	24 Dec 2020 07:33:33
User accepted default value 'Day 3 (Day 3)'	Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 20:38:05

US3032115

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 14:48:59

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:51:52
DataPoint Verified.		14 Apr 2021 20:02:56
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 20:38:05

US3032115

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 14:48:59

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:51:52
DataPoint Verified.		14 Apr 2021 20:02:56
User closed query 'Per GCL Lab Reconciliation: Saliva : Sample dated 14DEC2020 is reported under Illness Visits 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).		04 Jan 2021 18:44:43
Query 'Per GCL Lab Reconciliation: Saliva : Sample dated 14DEC2020 is reported under Illness Visits 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 'data updated' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	04 Jan 2021 14:40:41
User opened query 'Per GCL Lab Reconciliation: Saliva : Sample dated 14DEC2020 is reported under Illness Visits 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)	24 Dec 2020 07:33:22
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	16 Dec 2020 20:07:22
User entered '11 Dec 2020'	Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 20:38:05

**US3032115**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 09 Jun 2021 14:48:59**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:51:52
User accepted default value 'Day 5 (Day 5)'	Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 20:38:05



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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 14:48:59

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:51:52
DataPoint Verified.		14 Apr 2021 20:02:56
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	04 Jan 2021 14:45:23
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Linden DeBoer (b) (4)	04 Jan 2021 14:45:23
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	11 Dec 2020 20:38:05
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 14:48:59

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:51:52
DataPoint Verified.	(b) (4)	14 Apr 2021 20:02:56
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:48:04
User closed query 'Per GCL LAB reconciliation: Saliva: Day 5 sample dated 13DEC2020 is reported in PPD central lab with 14DEC2020 date. Please review the Preclarus and confirm the correct date in response. If there is a mismatch, then amend EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Jan 2021 10:47:50
Query 'Per GCL LAB reconciliation: Saliva: Day 5 sample dated 13DEC2020 is reported in PPD central lab with 14DEC2020 date. Please review the Preclarus and confirm the correct date in response. If there is a mismatch, then amend EDC or Preclarus as appropriate. Thank you.' answered with 'updated' (Site from DM).	Samantha Wieseler (b) (4)	19 Jan 2021 20:05:40
Signature has been broken.	(b) (4)	
User entered '14 Dec 2020' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	19 Jan 2021 20:05:34
User opened query 'Per GCL LAB reconciliation: Saliva: Day 5 sample dated 13DEC2020 is reported in PPD central lab with 14DEC2020 date. Please review the Preclarus and confirm the correct date in response. If there is a mismatch, then amend EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 04:11:21
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Signature has been broken.	(b) (4)	
User entered '13 Dec 2020' reason for change: Data Entry Error	Linden DeBoer (b) (4)	04 Jan 2021 14:45:23
User signature succeeded.	(b) (4)	
User entered empty.	Linden DeBoer (b) (4)	04 Jan 2021 14:45:23
	(b) (4)	
	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
	(b) (4)	
	Kelsey Kelley (b) (4)	11 Dec 2020 20:38:05
	(b) (4)	

**US3032115**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 09 Jun 2021 14:48:59**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:51:52
User accepted default value 'Day 7 (Day 7)'	Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 20:38:05

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 14:48:59

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:51:52
DataPoint Verified.		14 Apr 2021 20:02:56
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	04 Jan 2021 14:45:23
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Linden DeBoer (b) (4)	04 Jan 2021 14:45:23
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	11 Dec 2020 20:38:05
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 14:48:59

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	0 Apr 2021 20:51:52
DataPoint Verified.		4 Apr 2021 20:02:56
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	04 Jan 2021 14:45:23
	(b) (4)	
User entered '15 Dec 2020' reason for change: Data Entry Error	Linden DeBoer (b) (4)	04 Jan 2021 14:45:23
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	11 Dec 2020 20:38:05
	(b) (4)	

**US3032115**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 09 Jun 2021 14:48:59**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:51:52
User accepted default value 'Day 9 (Day 9)'	Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 20:38:05

US3032115

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 14:48:59

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:51:52
DataPoint Verified.		14 Apr 2021 20:02:56
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	04 Jan 2021 14:45:23
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Linden DeBoer (b) (4)	04 Jan 2021 14:45:23
reason for change: Data Entry Error	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	11 Dec 2020 20:38:05
	(b) (4)	

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**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 09 Jun 2021 14:48:59**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:51:52
DataPoint Verified.		14 Apr 2021 20:02:56
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 20:38:05



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**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 14:48:59**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:51:52
User accepted default value 'Day 14 (Day 14)'	Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 20:38:05

US3032115

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 14:48:59

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:51:52
DataPoint Verified.		14 Apr 2021 20:02:56
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	04 Jan 2021 14:45:23
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Linden DeBoer (b) (4)	04 Jan 2021 14:45:23
reason for change: Data Entry Error	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	11 Dec 2020 20:38:05
	(b) (4)	

**US3032115**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 14:48:59**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:51:52
DataPoint Verified.		14 Apr 2021 20:02:56
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 20:38:05

**US3032115**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 09 Jun 2021 14:48:59**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:51:52
User accepted default value 'Day 21 (Day 21)'	Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 20:38:05

US3032115

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 14:48:59

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:51:52
DataPoint Verified.		14 Apr 2021 20:02:56
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	04 Jan 2021 14:45:23
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Linden DeBoer (b) (4)	04 Jan 2021 14:45:23
reason for change: Data Entry Error	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	11 Dec 2020 20:38:05
	(b) (4)	

**US3032115**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 09 Jun 2021 14:48:59**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:51:52
DataPoint Verified.		14 Apr 2021 20:02:56
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 20:38:05

**US3032115**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 14:48:59**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:51:52
User accepted default value 'Day 28 (Day 28)'	Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 20:38:05

US3032115

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 14:48:59

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:51:52
DataPoint Verified.		14 Apr 2021 20:02:56
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	04 Jan 2021 14:45:23
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Linden DeBoer (b) (4)	04 Jan 2021 14:45:23
reason for change: Data Entry Error	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	11 Dec 2020 20:38:05
	(b) (4)	



US3032115

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 14:48:59

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:51:52
DataPoint Verified.		14 Apr 2021 20:02:56
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 20:38:05

**US3032115**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:48:59**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:51:31
DataPoint Verified.		14 Apr 2021 19:53:20
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:12:10

US3032115

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:48:59

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:51:31
DataPoint Verified.		14 Apr 2021 19:53:20
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered '09 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:12:10

**US3032115**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:48:59**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:51:31
DataPoint Verified.		14 Apr 2021 19:53:20
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered 'Clinic (Clinic)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:12:10

**US3032115**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:48:59**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:51:31
User entered 'SICKD1'	System	09 Dec 2020 17:12:10

US3032115

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:51:35
DataPoint Verified.		14 Apr 2021 19:54:45
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:13:18

US3032115

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:51:35
DataPoint Verified.		14 Apr 2021 19:54:45
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered '9 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:13:18

US3032115

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:59

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:51:35
DataPoint Verified.		14 Apr 2021 19:54:45
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered '09:09'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:13:18



**US3032115**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:48:59**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:51:35
User entered '9 Dec 2020 09:09'	System	09 Dec 2020 17:13:18

US3032115

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:59

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:51:35
DataPoint Verified.		14 Apr 2021 19:54:45
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered '154.9' cm	(b) (4) Kelsey Kelley (b) (4)	09 Dec 2020 17:13:18
DataPoint set to visible.	(b) (4) System	09 Dec 2020 17:12:10

US3032115

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:59

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:51:35
DataPoint Verified.		14 Apr 2021 19:54:45
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered '72' kg	(b) (4) Kelsey Kelley (b) (4)	09 Dec 2020 17:13:18
DataPoint set to visible.	(b) (4) System	09 Dec 2020 17:12:10

US3032115

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:51:35
DataPoint Verified.		14 Apr 2021 19:54:45
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered '36.3' C	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:13:18

US3032115

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:51:35
DataPoint Verified.		14 Apr 2021 19:54:45
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:13:18

US3032115

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:51:35
DataPoint Verified.		14 Apr 2021 19:54:45
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:13:18

US3032115

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:51:35
DataPoint Verified.		14 Apr 2021 19:54:45
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered '85'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:13:18

**US3032115**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:48:59**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:51:35
User entered 'bpm'	System	09 Dec 2020 17:13:18



US3032115

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:51:35
DataPoint Verified.		14 Apr 2021 19:54:45
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered '22'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:13:18

US3032115

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:51:35
User entered 'breaths/min'	System	09 Dec 2020 17:13:18

US3032115

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:51:35
DataPoint Verified.		14 Apr 2021 19:54:45
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered '122'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:13:18

**US3032115**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:48:59**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:51:35
User entered 'mmHg'	System	09 Dec 2020 17:13:18

US3032115

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:51:35
DataPoint Verified.		14 Apr 2021 19:54:45
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered '84'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:13:18

US3032115

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:51:35
User entered 'mmHg'	System	09 Dec 2020 17:13:18

**US3032115**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:48:59**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:51:35

US3032115

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:48:59

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:51:35



US3032115

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:48:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:51:39
DataPoint Verified.		14 Apr 2021 19:55:22
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:13:23

US3032115

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:48:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:51:39
DataPoint Verified.		14 Apr 2021 19:55:22
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered '9 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:13:23

US3032115

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 14:48:59

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:51:43
DataPoint Verified.		14 Apr 2021 19:59:16
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:13:27

US3032115

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 14:48:59

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:51:43
DataPoint Verified.		14 Apr 2021 19:59:16
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:13:27

US3032115

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:48:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:33
DataPoint Verified.		07 Apr 2021 20:19:59
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:48:04
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:13:02

US3032115

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:48:59

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:33
DataPoint Verified.		07 Apr 2021 20:19:59
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:48:04
User entered '28 Jan 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:13:02

US3032115

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:48:59

[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 20:52:33
DataPoint Verified.		07 Apr 2021 20:19:59
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:48:04
User entered 'Clinic (Clinic)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:13:02

**US3032115**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:48:59**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:33
User entered 'UNBLND_DECIDE'	System	28 Jan 2021 19:13:02



US3032115

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:48:59

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:33
DataPoint Verified.		07 Apr 2021 20:20:07
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:48:04
User entered '28 Jan 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:13:20

**US3032115**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:48:59**

[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 20:52:33
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:43:09

US3032115

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:48:59

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:33
DataPoint Verified.		07 Apr 2021 20:20:07
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:48:04
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:13:20

**US3032115**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:48:59**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:33
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
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 11:43:09

US3032115

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:48:59

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:33
DataPoint Verified.		07 Apr 2021 20:20:07
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:48:04
User entered '28 Jan 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:13:20

US3032115

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:48:59

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:33
DataPoint Verified.		07 Apr 2021 20:20:07
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:48:04
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:13:20

US3032115

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:48:59

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:33
DataPoint Verified.		07 Apr 2021 20:20:07
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:48:04
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:13:20

US3032115

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:48:59

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:33
DataPoint Verified.		07 Apr 2021 20:20:07
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:48:04
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:13:20



US3032115

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:48:59

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:33
DataPoint Verified.		07 Apr 2021 20:20:07
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:48:04
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:13:20

**US3032115**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:48:59**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:33
User entered empty.	System	28 Jan 2021 19:13:20

**US3032115**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:48:59**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:33
User entered empty.	System	28 Jan 2021 19:13:20

US3032115

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:48:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:33
DataPoint Verified.		07 Apr 2021 20:20:26
User closed query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, no immunogenicity sample was received for the Patient Decision Visit / OL-D1 on 28JAN2021. Please clarify if sample was shipped and provide the accession number and tracking detail in the query response box, as appropriate. ' (Site from DM). Query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, no immunogenicity sample was received for the Patient Decision Visit / OL-D1 on 28JAN2021. Please clarify if sample was shipped and provide the accession number and tracking detail in the query response box, as appropriate. ' answered with 'Accession Number: 1F63403 received on the 10th of feb' (Site from DM). User opened query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, no immunogenicity sample was received for the Patient Decision Visit / OL-D1 on 28JAN2021. Please clarify if sample was shipped and provide the accession number and tracking detail in the query response box, as appropriate. ' (Site from DM). User signature succeeded.	Samantha Wieseler (b) (4) (b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:07  11 Feb 2021 13:48:08
User entered 'Yes (Y)'	Keith Vrbicky (b) (4) (b) (4) Kelsey Kelley (b) (4) (b) (4)	30 Jan 2021 16:48:04  28 Jan 2021 19:13:30

US3032115

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:48:59

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:33
DataPoint Verified.		07 Apr 2021 20:20:26
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:48:04
User entered '28 Jan 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:13:30

US3032115

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:48:59

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:33
DataPoint Verified.		07 Apr 2021 20:20:26
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:48:04
User entered '10:00'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:13:30

**US3032115**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:48:59**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:33
User entered '28 Jan 2021 10:00'	System	28 Jan 2021 19:13:30

US3032115

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:48:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:33
DataPoint Verified.		07 Apr 2021 20:20:35
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:48:04
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:13:39



US3032115

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:48:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:33
DataPoint Verified.		07 Apr 2021 20:20:35
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:48:04
User entered '28 Jan 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:13:39

US3032115

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:48:59

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:33
DataPoint Verified.		07 Apr 2021 20:20:35
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:48:04
User entered '09:29'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Jan 2021 19:13:39

**US3032115**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 14:48:59**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:52:33
User entered '28 Jan 2021 09:29'	System	28 Jan 2021 19:13:39

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 14:48:59

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:09:00
DataPoint Verified.		17 Dec 2020 21:23:49
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 17:11:45

**US3032115**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:48:59**

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:21:12
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:26:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:25:32
User entered 'USA-US032-2021-mRNA-1273-P301000001'	System	04 Jan 2021 18:24:27
User entered 'New'	(b) (4), (b) (6)	04 Jan 2021 18:24:27

US3032115

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:48:59

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:21:12
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User closed query 'PV Query: The event term 'bilateral pneumonia/sepsis' contains 2 separate PT's and therefore cannot be combined into one event. Additionally, per the discharge summary, the CT chest was negative. If pneumonia was NOT diagnosed, please consider removing it from the event term. If pneumonia was diagnosed, please separate the event into 2 separate terms.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:00:49
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Sepsis, bacteraemia, viraemia and fungaemia NEC, PT: Sepsis, LLT: Sepsis NOS - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	26 Feb 2021 00:12:07
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	26 Feb 2021 00:12:07
Query 'PV Query: The event term 'bilateral pneumonia/sepsis' contains 2 separate PT's and therefore cannot be combined into one event. Additionally, per the discharge summary, the CT chest was negative. If pneumonia was NOT diagnosed, please consider removing it from the event term. If pneumonia was diagnosed, please separate the event into 2 separate terms.' answered with 'Thank you. 2 seperate AEs have been created based off your recommendation. ' (Site from Safety).	Chelsie Nutsch (b) (4) (b) (4)	25 Feb 2021 18:25:47
Data point term sent to Coder	System	25 Feb 2021 18:25:24
Signature has been broken.	Chelsie Nutsch (b) (4) (b) (4)	25 Feb 2021 18:25:08
User entered 'SEPSIS of unknown origin' reason for change: New Information	Chelsie Nutsch (b) (4) (b) (4)	25 Feb 2021 18:25:08

US3032115

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:48:59

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'PV Query: The event term 'bilateral pneumonia/sepsis' contains 2 separate PT's and therefore cannot be combined into one event. Additionally, per the discharge summary, the CT chest was negative. If pneumonia was NOT diagnosed, please consider removing it from the event term. If pneumonia was diagnosed, please separate the event into 2 separate terms.' (Site from Safety).	(b) (4), (b) (6)	23 Feb 2021 21:33:27
User closed query 'PV Query: Thank you for confirming that event term will be split as it contains multiple events. Please leave query open until EDC has been updated.' (Site from Safety).	(b) (4), (b) (6)	22 Feb 2021 17:13:42
Query 'PV Query: Thank you for confirming that event term will be split as it contains multiple events. Please leave query open until EDC has been updated.' answered with 'last answer was "will update if update is necessary". SAE was reported as combined term therefore term has been left combined. ' (Site from Safety).	Samantha Wieseler (b) (4) (b) (4)	19 Feb 2021 18:00:31
User opened query 'PV Query: Thank you for confirming that event term will be split as it contains multiple events. Please leave query open until EDC has been updated.' (Site from Safety).	(b) (4), (b) (6)	18 Feb 2021 19:34:38
User closed query 'PV Query: The event term 'bilateral pneumonia/sepsis' contains multiple event terms. Please consider separating them into separate events.' (Site from Safety).	(b) (4), (b) (6)	18 Feb 2021 19:34:38
Query 'PV Query: The event term 'bilateral pneumonia/sepsis' contains multiple event terms. Please consider separating them into separate events.' answered with 'will update if update is needed. ' (Site from Safety).	Samantha Wieseler (b) (4) (b) (4)	17 Feb 2021 19:20:31
User opened query 'PV Query: The event term 'bilateral pneumonia/sepsis' contains multiple event terms. Please consider separating them into separate events.' (Site from Safety).	(b) (4), (b) (6)	16 Feb 2021 16:28:44
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	12 Feb 2021 19:54:32
Data point term sent to Coder	System	09 Feb 2021 01:50:20
DataPoint Un-verified.	Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 01:49:27

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:48:59

[Adverse event](#)

Audit	User	Time (GMT)
Coding entries removed.	Kelsey Kelley (b) (4)	09 Feb 2021 01:49:27
Signature has been broken.	Kelsey Kelley (b) (4)	09 Feb 2021 01:49:27
User entered 'BILATERAL PNEUMONIA/Sepsis' reason for change: New Information	Kelsey Kelley (b) (4)	09 Feb 2021 01:49:27
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:23:53
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:22
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Pneumonia, LLT: Bilateral pneumonia - version MedDRA\\23.0.	Coder Import (b) (4)	16 Dec 2020 16:33:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Dec 2020 16:33:57
Data point term sent to Coder	System	16 Dec 2020 16:33:04
Coding entries removed.	Kelsey Kelley (b) (4)	16 Dec 2020 16:32:47
Signature has been broken.	Kelsey Kelley (b) (4)	16 Dec 2020 16:32:47
User entered 'bilateral pneumonia' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	16 Dec 2020 16:32:47
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: Suspected COVID-19, LLT: Suspected COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4)	09 Dec 2020 20:53:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Dec 2020 20:53:58
Data point term sent to Coder	System	09 Dec 2020 20:52:29
User entered 'Suspected covid-19'	Kelsey Kelley (b) (4)	09 Dec 2020 20:51:53



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:48:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:23:53
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	09 Dec 2020 20:51:53
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:48:59**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:23:53
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	09 Dec 2020 20:51:53

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:48:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:23:53
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	09 Dec 2020 20:51:53

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:48:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:21:12
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
DataPoint Un-verified.	Chelsie Nutsch (b) (4)	25 Feb 2021 18:25:08
Signature has been broken.	Chelsie Nutsch (b) (4)	25 Feb 2021 18:25:08
User entered '21 Dec 2020' reason for change: Data Entry Error	Chelsie Nutsch (b) (4)	25 Feb 2021 18:25:08
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:23:53
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Dec 2020 20:53:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Dec 2020 20:53:04
User entered '5 Dec 2020' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	09 Dec 2020 20:53:04
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Dec 2020 20:51:53
User entered empty.	Kelsey Kelley (b) (4)	09 Dec 2020 20:51:53

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:48:59**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:23:53
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	09 Dec 2020 20:51:53

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:48:59**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Dec 2020 20:51:53

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:48:59

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:21:12
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
DataPoint Un-verified.	(b) (4)	09 Feb 2021 01:50:57
Signature has been broken.	Kelsey Kelley (b) (4)	09 Feb 2021 01:50:57
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	09 Feb 2021 01:50:57
DataPoint Verified.	Kelsey Kelley (b) (4)	17 Dec 2020 21:23:53
User signature succeeded.	(b) (4), (b) (6)	10 Dec 2020 16:21:15
User entered 'Yes (Y)'	Keith Vrbicky (b) (4)	09 Dec 2020 20:51:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:48:59

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:21:12
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System). Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	09 Feb 2021 01:50:57
DataPoint Un-verified.	Kelsey Kelley (b) (4)	09 Feb 2021 01:50:57
Signature has been broken.	Kelsey Kelley (b) (4)	09 Feb 2021 01:50:57
User entered '24 Dec 2020' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	09 Feb 2021 01:50:57
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	09 Feb 2021 01:50:26
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:23:53
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered empty.	Kelsey Kelley (b) (4)	09 Dec 2020 20:51:53



**US3032115**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:48:59**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:23:53
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	09 Dec 2020 20:51:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:48:59

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' canceled (Site from Safety).	(b) (4), (b) (6)	16 Feb 2021 16:28:24
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 19:02:43
User entered empty.	System	09 Dec 2020 20:51:53

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:48:59

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:21:12
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:26:59
DataPoint Un-verified.	(b) (4)	
	Kelsey Kelley (b) (4)	30 Dec 2020 16:31:27
Signature has been broken.	(b) (4)	
	Kelsey Kelley (b) (4)	30 Dec 2020 16:31:27
User entered 'Grade 4 (Grade 4)' reason for change:	(b) (4)	
Data Entry Error	Kelsey Kelley (b) (4)	30 Dec 2020 16:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:23:53
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Kelsey Kelley (b) (4)	09 Dec 2020 20:51:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:48:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:21:12
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:26:59
DataPoint Un-verified.	(b) (4)	
	Kelsey Kelley (b) (4)	30 Dec 2020 16:31:27
Signature has been broken.	(b) (4)	
	Kelsey Kelley (b) (4)	30 Dec 2020 16:31:27
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Kelsey Kelley (b) (4)	30 Dec 2020 16:31:27
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:23:53
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	09 Dec 2020 20:51:53
	(b) (4)	

**US3032115**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:48:59**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:23:53
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	09 Dec 2020 20:51:53
	(b) (4)	

**US3032115**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:48:59**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:23:53
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	09 Dec 2020 20:51:53

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:48:59

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:21:12
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).		12 Feb 2021 15:03:19
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'records sent' (Site from Safety).	Samantha Wieseler (b) (4)	11 Feb 2021 20:06:28
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 16:15:57
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:26:59
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4)	30 Dec 2020 16:35:52
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).		30 Dec 2020 16:35:52
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	30 Dec 2020 16:31:27
DataPoint Un-verified.	Kelsey Kelley (b) (4)	30 Dec 2020 16:31:27
Signature has been broken.	(b) (4) Kelsey Kelley (b) (4)	30 Dec 2020 16:31:27

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '1' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	30 Dec 2020 16:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 21:23:53
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 20:51:53



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Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:21:12
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:26:59
DataPoint Un-verified.	(b) (4)	
	Kelsey Kelley (b) (4)	30 Dec 2020 16:35:52
Signature has been broken.	(b) (4)	
	Kelsey Kelley (b) (4)	30 Dec 2020 16:35:52
User entered '21 Dec 2020' reason for change: Data Entry Error	(b) (4)	
	Kelsey Kelley (b) (4)	30 Dec 2020 16:35:52
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:23:53
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	09 Dec 2020 20:51:53
	(b) (4)	

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:21:12
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so' (Site from Safety).	(b) (4), (b) (6)	02 Feb 2021 15:32:28
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so' answered with 'will update once medical records are received' (Site from Safety).	Samantha Wieseler (b) (4)	01 Feb 2021 20:07:33
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so' (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 17:42:25
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:26:59
DataPoint Un-verified.	Kelsey Kelley (b) (4)	30 Dec 2020 16:35:52
Signature has been broken.	Kelsey Kelley (b) (4)	30 Dec 2020 16:35:52
User entered '24 Dec 2020' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	30 Dec 2020 16:35:52
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:23:53
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered empty.	Kelsey Kelley (b) (4)	09 Dec 2020 20:51:53

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:21:12
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:26:59
DataPoint Un-verified.	(b) (4)	30 Dec 2020 16:31:45
Signature has been broken.	Kelsey Kelley (b) (4)	30 Dec 2020 16:31:45
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	30 Dec 2020 16:31:45
DataPoint Verified.	Kelsey Kelley (b) (4)	30 Dec 2020 16:31:45
User signature succeeded.	(b) (4)	17 Dec 2020 21:23:53
User entered empty.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
	(b) (4)	09 Dec 2020 20:51:53

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:23:53
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	09 Dec 2020 20:51:53
	(b) (4)	

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:23:53
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	09 Dec 2020 20:51:53

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:23:53
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	09 Dec 2020 20:51:53

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:23:53
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	09 Dec 2020 20:51:53

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:23:53
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Dec 2020 20:53:04
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	System	09 Dec 2020 20:53:04
User opened query 'Data is required. Please complete.' (Site from System).	Kelsey Kelley (b) (4)	09 Dec 2020 20:53:04
User entered empty.	(b) (4)	
	System	09 Dec 2020 20:51:53
	Kelsey Kelley (b) (4)	09 Dec 2020 20:51:53
	(b) (4)	



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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:23:53
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Dec 2020 20:53:04
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	System	09 Dec 2020 20:53:04
User opened query 'Data is required. Please complete.' (Site from System).	Kelsey Kelley (b) (4)	09 Dec 2020 20:53:04
User entered empty.	(b) (4)	
	System	09 Dec 2020 20:51:53
	Kelsey Kelley (b) (4)	09 Dec 2020 20:51:53
	(b) (4)	

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:23:53
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Kelsey Kelley (b) (4)	09 Dec 2020 20:51:53
	(b) (4)	

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[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:23:53
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	09 Dec 2020 20:51:53
	(b) (4)	

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:23:53
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered 'I'	(b) (4) Kelsey Kelley (b) (4)	09 Dec 2020 20:51:53
	(b) (4)	

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:23:53
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	09 Dec 2020 20:51:53
	(b) (4)	

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Form: Adverse Events (1)

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:21:12
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:39:02
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'Subject is recovered/resolved' (Site from Safety).	Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 01:51:14
DataPoint Un-verified.	Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 01:50:26
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 01:50:26
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 01:50:26
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 16:15:48
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	02 Feb 2021 15:32:41
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'will update when subject states resolution' (Site from Safety).	Samantha Wieseler (b) (4) (b) (4)	01 Feb 2021 20:07:18

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[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 17:41:27
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).		19 Jan 2021 15:12:23
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'will up date accordingly when available' (Site from Safety).	Samantha Wieseler (b) (4) (b) (4)	15 Jan 2021 01:03:21
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	14 Jan 2021 20:18:48
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).		11 Jan 2021 16:30:04
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'has not resolved yet' (Site from Safety).	Samantha Wieseler (b) (4) (b) (4)	09 Jan 2021 15:09:52
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 19:06:00
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:23:53
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	10 Dec 2020 16:21:15

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[Outcome](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Dec 2020 20:53:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Dec 2020 20:53:04
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	09 Dec 2020 20:53:04
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Dec 2020 20:51:53
User entered empty.	Kelsey Kelley (b) (4)	09 Dec 2020 20:51:53



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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:23:53
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	09 Dec 2020 20:51:53
	(b) (4)	

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:21:12
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User closed query 'Per DM CLR: Narrative = NEGATIVE FOR RSV, COVID, INFLUENZA, ETC. HER LACTIC ACID WAS 1.7, WBC 6.2. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Mar 2021 01:56:33
User closed query 'Per DM CLR: Narrative = NEGATIVE RESPIRATORY PANEL 21DEC. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 01:56:30
User closed query 'Per DM CLR: Narrative = CT OF CHEST/ABD. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 01:56:28
User closed query 'Per DM CLR: Narrative = SHE WAS HYPOTENSIVE. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 01:56:01
Signature has been broken.	Chelsie Nutsch (b) (4) (b) (4)	16 Mar 2021 19:44:05

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Audit	User	Time (GMT)
User entered 'THE SUBJECT IS CALLED. SHE REPORTS SHE WAS HOSPITALIZED 21 DEC-24 DEC DUE TO SEPSIS OF UNKNOWN ORIGIN. SHE WAS NOT IN THE ICU. SHE CONTINUES TO FEEL UNWELL, BUT IS CURRENTLY AT HOME. MEDICAL RECORDS ARE REQUESTED. SHE WILL INFORM SITE IF THERE ARE ANY OTHER CHANGES. NO QUESTIONS OR CONCERNS. SHE HAS CONTINUED TO TEST NEGATIVE FOR COVID. UPDATE 05 FEB: MEDICAL RECORDS REVIEWED. THE SUBJECTS SYMPTOMS BEGAN 05 DEC 2020. SHE DID HAVE AN ER VISIT ON 09 DEC 2020 AND WAS DISCHARGED HOME WITH NEW MEDICATIONS. HER ILLNESS CONTINUED. SHE WAS SEEN SEVERAL TIMES BY HER PCP AND TOOK MULTIPLE COURSES OF ABX'S AND STEROIDS. ON 21 DEC 2020 SHE AGAIN SOUGHT CARE THROUGH THE ER WHILE EXPERIENCING FEVER, CHILLS, PLEURISY, AND SHORTNESS OF BREATH. HER CT OF CHEST/ABD WAS NEGATIVE. SHE WAS NEGATIVE FOR RSV, COVID, INFLUENZA, ETC. HER LACTIC ACID WAS 1.7, WBC 6.2, AND SHE WAS HYPOTENSIVE. SHE WAS ADMITTED TO THE HOSPITAL FOR SEPSIS OF UNKNOWN ORIGIN. SHE WAS NOT IN THE ICU. SHE WAS STARTED ON VANCOMYCIN AND AZTREONAM. THE SUBJECT WAS DISCHARGED 24 DEC 2020 ONCE MEDICALLY STABLE. DATES OF NEGATIVE COVID TESTING: STUDY COVID TEST: 09DEC2020, ER RAPID TEST 10DEC, TEST @ PCP 18DEC, RAPID ER TEST 21DEC, NEGATIVE ANTIBODY TEST 22DEC. NEGATIVE RESPIRATORY PANEL 22DEC' reason for change: New Information	Chelsie Nutsch (b) (4) (b) (4)	16 Mar 2021 19:44:05
Query 'Per DM CLR: Narrative = NEGATIVE RESPIRATORY PANEL 21DEC. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'data updated' (Site from DM).	Chelsie Nutsch (b) (4) (b) (4)	16 Mar 2021 19:43:31

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EAB) (1725)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Narrative = SHE WAS HYPOTENSIVE. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' answered with 'hypotension is consistent with a diagnosis of sepsis, therefore no additional AE is necessary. ' (Site from DM).	Chelsie Nutsch (b) (4)	16 Mar 2021 19:43:25
Query 'Per DM CLR: Narrative = NEGATIVE FOR RSV, COVID, INFLUENZA, ETC. HER LACTIC ACID WAS 1.7, WBC 6.2. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'data updated' (Site from DM).	Chelsie Nutsch (b) (4)	16 Mar 2021 19:43:01
Query 'Per DM CLR: Narrative = CT OF CHEST/ABD. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'data updated' (Site from DM).	Chelsie Nutsch (b) (4)	16 Mar 2021 19:42:54
User opened query 'Per DM CLR: Narrative = NEGATIVE RESPIRATORY PANEL 21DEC. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	28 Feb 2021 01:58:54
User opened query 'Per DM CLR: Narrative = SHE WAS HYPOTENSIVE. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Feb 2021 01:58:48
User opened query 'Per DM CLR: Narrative = NEGATIVE FOR RSV, COVID, INFLUENZA, ETC. HER LACTIC ACID WAS 1.7, WBC 6.2. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	28 Feb 2021 01:58:29
User opened query 'Per DM CLR: Narrative = CT OF CHEST/ABD. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	28 Feb 2021 01:58:23
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'THE SUBJECT IS CALLED. SHE REPORTS SHE WAS HOSPITALIZED 21 DEC-24 DEC DUE TO SEPSIS OF UNKNOWN ORIGIN. SHE WAS NOT IN THE ICU. SHE CONTINUES TO FEEL UNWELL, BUT IS CURRENTLY AT HOME. MEDICAL RECORDS ARE REQUESTED. SHE WILL INFORM SITE IF THERE ARE ANY OTHER CHANGES. NO QUESTIONS OR CONCERNS. SHE HAS CONTINUED TO TEST NEGATIVE FOR COVID. UPDATE 05 FEB: MEDICAL RECORDS REVIEWED. THE SUBJECTS SYMPTOMS BEGAN 05 DEC 2020. SHE DID HAVE AN ER VISIT ON 09 DEC 2020 AND WAS DISCHARGED HOME WITH NEW MEDICATIONS. HER ILLNESS CONTINUED. SHE WAS SEEN SEVERAL TIMES BY HER PCP AND TOOK MULTIPLE COURSES OF ABX'S AND STEROIDS. ON 21 DEC 2020 SHE AGAIN SOUGHT CARE THROUGH THE ER WHILE EXPERIENCING FEVER, CHILLS, PLEURISY, AND SHORTNESS OF BREATH. HER CT OF CHEST/ABD WAS NEGATIVE. SHE WAS NEGATIVE FOR RSV, COVID, INFLUENZA, ETC. HER LACTIC ACID WAS 1.7, WBC 6.2, AND SHE WAS HYPOTENSIVE. SHE WAS ADMITTED TO THE HOSPITAL FOR SEPSIS OF UNKNOWN ORIGIN. SHE WAS NOT IN THE ICU. SHE WAS STARTED ON VANCOMYCIN AND AZTREONAM. THE SUBJECT WAS DISCHARGED 24 DEC 2020 ONCE MEDICALLY STABLE. DATES OF NEGATIVE COVID TESTING: STUDY COVID TEST: 09DEC2020, ER RAPID TEST 10DEC, TEST @ PCP 18DEC, RAPID ER TEST 21DEC, NEGATIVE ANTIBODY TEST 22DEC. NEGATIVE RESPIRATORY PANEL 21DEC' reason for change: New Information	Chelsie Nutsch (b) (4) (b) (4)	10 Feb 2021 16:22:16
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	09 Feb 2021 13:39:15

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Audit	User	Time (GMT)
User closed query 'PV Query: Please provide dates of COVID testing.' (Site from Safety).	(b) (4), (b) (6)	09 Feb 2021 13:39:05
Query 'PV Query: Please provide dates of COVID testing.' answered with 'Updated data ' (Site from Safety).	Kelsey Kelley (b) (4)	09 Feb 2021 02:02:05
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Updated data ' (Site from Safety).	Kelsey Kelley (b) (4)	09 Feb 2021 02:00:57
DataPoint Un-verified.	Kelsey Kelley (b) (4)	09 Feb 2021 02:00:40
Signature has been broken.	Kelsey Kelley (b) (4)	09 Feb 2021 02:00:40
User entered 'THE SUBJECT IS CALLED. SHE REPORTS SHE WAS HOSPITALIZED 21 DEC-24 DEC DUE TO SEPSIS OF UNKNOWN ORIGIN. SHE WAS NOT IN THE ICU. SHE CONTINUES TO FEEL UNWELL, BUT IS CURRENTLY AT HOME. MEDICAL RECORDS ARE REQUESTED. SHE WILL INFORM SITE IF THERE ARE ANY OTHER CHANGES. NO QUESTIONS OR CONCERNS. SHE HAS CONTINUED TO TEST NEGATIVE FOR COVID. UPDATE 05 Feb: medical records reviewed. The subjects symptoms began 05 dec 2020. she did have an ER visit on 09 Dec 2020 and was discharged home with new medications. her illness continued. she was seen several times by her pcp and took multiple courses of Abx's and steroids. on 21 dec 2020 she again sought care through the ER while experiencing fever, chills, pleurisy, and shortness of breath. her ct of chest/abd was negative. she was negative for rsv, covid, influenza, etc. her lactic acid was 1.7, wbc 6.2, and she was hypotensive. she was admitted to the hospital for sepsis of unknown origin. she was not in the ICU. she was started on vancomycin and aztreonam. the subject was discharged 24 Dec 2020 once medically stable.' reason for change: New Information	Kelsey Kelley (b) (4)	09 Feb 2021 02:00:40

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 16:15:42
User opened query 'PV Query: Please provide dates of COVID testing.' (Site from Safety).		08 Feb 2021 16:15:36
DataPoint Verified.		05 Feb 2021 20:14:37
User closed query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).		02 Feb 2021 15:32:46
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		02 Feb 2021 15:32:45
User closed query 'PV Query: Please provide dates of COVID testing.' (Site from Safety).		02 Feb 2021 15:32:43
Query 'PV Query: Please provide dates of COVID testing.' answered with 'will update when records are received' (Site from Safety).	Samantha Wieseler (b) (4)	01 Feb 2021 20:07:00
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'non at this time' (Site from Safety).	Samantha Wieseler (b) (4)	01 Feb 2021 20:06:48
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' answered with 'none' (Site from Safety).	Samantha Wieseler (b) (4)	01 Feb 2021 20:06:38
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 17:42:08
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		29 Jan 2021 17:41:09
User opened query 'PV Query: Please provide dates of COVID testing.' (Site from Safety).		29 Jan 2021 17:40:37
User closed query 'PV Query: Please confirm if sepsis meets criteria for separate AE/SAE reporting.' (Site from Safety).		22 Jan 2021 16:21:59

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:48:59

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 16:21:55
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		22 Jan 2021 16:21:50
User closed query 'PV Query: Please provide dates of COVID testing.' (Site from Safety).		22 Jan 2021 16:21:46
Query 'PV Query: Please provide dates of COVID testing.' answered with 'will update accordingly' (Site from Safety).	Samantha Wieseler (b) (4)	21 Jan 2021 22:21:02
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'will provide when records are available' (Site from Safety).	Samantha Wieseler (b) (4)	21 Jan 2021 22:20:52
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'will update when an event outcome is available' (Site from Safety).	Samantha Wieseler (b) (4)	21 Jan 2021 22:20:36
Query 'PV Query: Please confirm if sepsis meets criteria for separate AE/SAE reporting.' answered with 'Sepsis did not meet criteria for separate AE' (Site from Safety).	Samantha Wieseler (b) (4)	21 Jan 2021 22:20:19
User opened query 'PV Query: Please confirm if sepsis meets criteria for separate AE/SAE reporting.' (Site from Safety).	(b) (4), (b) (6)	21 Jan 2021 17:55:31
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).		21 Jan 2021 17:55:24
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		21 Jan 2021 17:55:13



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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide dates of COVID testing.' (Site from Safety).	(b) (4), (b) (6)	21 Jan 2021 17:55:04
User closed query 'PV Query: Please confirm if sepsis meets criteria for separate AE/SAE reporting.' (Site from Safety).		19 Jan 2021 15:12:21
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		19 Jan 2021 15:12:20
User closed query 'PV Query: Please provide dates of COVID testing.' (Site from Safety).		19 Jan 2021 15:12:18
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:26:59
Query 'PV Query: Please confirm if sepsis meets criteria for separate AE/SAE reporting.' answered with 'will update accordingly' (Site from Safety).	(b) (4)	
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'will update accordingly' (Site from Safety).	Samantha Wieseler (b) (4)	15 Jan 2021 01:04:00
Query 'PV Query: Please provide dates of COVID testing.' answered with 'will update accordingly' (Site from Safety).	(b) (4)	
User opened query 'PV Query: Please confirm if sepsis meets criteria for separate AE/SAE reporting.' (Site from Safety).	Samantha Wieseler (b) (4)	15 Jan 2021 01:03:39
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4)	
User opened query 'PV Query: Please provide dates of COVID testing.' (Site from Safety).	Samantha Wieseler (b) (4)	15 Jan 2021 01:03:30
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4)	
User opened query 'PV Query: Please provide dates of COVID testing.' (Site from Safety).	(b) (4), (b) (6)	14 Jan 2021 20:18:54
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		14 Jan 2021 20:18:41
User opened query 'PV Query: Please provide dates of COVID testing.' (Site from Safety).		14 Jan 2021 20:18:31
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		11 Jan 2021 16:30:09
User closed query 'PV Query: Please provide dates of COVID testing.' (Site from Safety).		11 Jan 2021 16:30:07

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please confirm if sepsis meets criteria for separate AE/SAE reporting. (Site from Safety).	(b) (4), (b) (6)	11 Jan 2021 16:30:05
Query 'PV Query: Please confirm if sepsis meets criteria for separate AE/SAE reporting. ' answered with 'will update accordingly' (Site from Safety).	Samantha Wieseler (b) (4)	09 Jan 2021 15:11:07
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' answered with 'will update accordingly' (Site from Safety).	Samantha Wieseler (b) (4)	09 Jan 2021 15:10:31
Query 'PV Query: Please provide dates of COVID testing. ' answered with 'will update accordingly' (Site from Safety).	Samantha Wieseler (b) (4)	09 Jan 2021 15:10:22
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 19:03:20
User opened query 'PV Query: Please provide dates of COVID testing. ' (Site from Safety).		07 Jan 2021 19:00:21
User opened query 'PV Query: Please confirm if sepsis meets criteria for separate AE/SAE reporting. ' (Site from Safety).		07 Jan 2021 18:59:07
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	30 Dec 2020 16:34:33
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	30 Dec 2020 16:34:33
DataPoint Un-verified.	Kelsey Kelley (b) (4)	30 Dec 2020 16:34:33
Signature has been broken.	Kelsey Kelley (b) (4)	30 Dec 2020 16:34:33
User entered 'The subject is called. She reports she was hospitalized 21 Dec-24 Dec due to sepsis of unknown origin. She was not in the ICU. She continues to feel unwell, but is currently at home. Medical records are requested. She will inform site if there are any other changes. No questions or concerns. She has continued to test negative for Covid.' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	30 Dec 2020 16:34:33

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	30 Dec 2020 16:31:27
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:23:53
User signature succeeded.	Keith Vrbicky (b) (4)	10 Dec 2020 16:21:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	09 Dec 2020 20:51:53
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:48:59**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Dec 2020 16:31:27
User entered '0'	System	09 Dec 2020 20:51:53

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:48:59**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Dec 2020 20:51:53

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:48:59**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	30 Dec 2020 16:31:45

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:48:59**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:07:52

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Folder: Adverse Events

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:07:52
DataPoint Verified.		07 Apr 2021 20:21:12
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Pneumonia, LLT: Bilateral pneumonia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	25 Feb 2021 18:31:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Feb 2021 18:31:06
Data point term sent to Coder	System	25 Feb 2021 18:30:35
User entered 'Bilateral Pneumonia'	Chelsie Nutsch (b) (4)	25 Feb 2021 18:30:12



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:48:59**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:07:52
DataPoint Verified.		07 Apr 2021 20:21:12
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'Yes (Y)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	25 Feb 2021 18:30:12

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:48:59**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:07:52
DataPoint Verified.		07 Apr 2021 20:21:12
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'No (N)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	25 Feb 2021 18:30:12

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Folder: Adverse Events

Form: Adverse Events (2)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:07:52
DataPoint Verified.		07 Apr 2021 20:21:12
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'No (N)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	25 Feb 2021 18:30:12

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:48:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:07:52
DataPoint Verified.		07 Apr 2021 20:21:12
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered '5 Dec 2020'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	25 Feb 2021 18:30:12

**US3032115**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:48:59**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:07:52
DataPoint Verified.		07 Apr 2021 20:21:12
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered empty.	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	25 Feb 2021 18:30:12

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:48:59**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:07:52
User entered empty.	System	25 Feb 2021 18:30:12

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:48:59**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:07:52
DataPoint Verified.		07 Apr 2021 20:21:12
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'No (N)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	25 Feb 2021 18:30:12

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:48:59

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:07:52
DataPoint Verified.		07 Apr 2021 20:21:12
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered '20 Dec 2020'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	25 Feb 2021 18:30:12



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:48:59**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:07:52
DataPoint Verified.		07 Apr 2021 20:21:12
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered empty.	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	25 Feb 2021 18:30:12

**US3032115**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:48:59**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:07:52
User entered empty.	System	25 Feb 2021 18:30:12

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:48:59

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:07:52
DataPoint Verified.		07 Apr 2021 20:21:12
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	25 Feb 2021 18:30:12

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:48:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:07:52
DataPoint Verified.		07 Apr 2021 20:21:12
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'No (N)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	25 Feb 2021 18:30:12

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:48:59

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:07:52
DataPoint Verified.		07 Apr 2021 20:21:12
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered '0'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	25 Feb 2021 18:30:12

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Folder: Adverse Events

Form: Adverse Events (2)

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:07:52
DataPoint Verified.		07 Apr 2021 20:21:12
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered '0'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	25 Feb 2021 18:30:12

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:48:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:07:52
DataPoint Verified.		07 Apr 2021 20:21:12
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered '0'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	25 Feb 2021 18:30:12

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:48:59

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:07:52
DataPoint Verified.		07 Apr 2021 20:21:12
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered empty.	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	25 Feb 2021 18:30:12



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Folder: Adverse Events

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Generated On: 09 Jun 2021 14:48:59

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:07:52
DataPoint Verified.		07 Apr 2021 20:21:12
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered empty.	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	25 Feb 2021 18:30:12

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:48:59**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:07:52
DataPoint Verified.		07 Apr 2021 20:21:12
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered empty.	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	25 Feb 2021 18:30:12

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:48:59**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:07:52
DataPoint Verified.		07 Apr 2021 20:21:12
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered empty.	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	25 Feb 2021 18:30:12

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Folder: Adverse Events

Form: Adverse Events (2)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:07:52
DataPoint Verified.		07 Apr 2021 20:21:12
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered '0'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	25 Feb 2021 18:30:12

**US3032115**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:07:52
DataPoint Verified.		07 Apr 2021 20:21:12
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered '0'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	25 Feb 2021 18:30:12

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Folder: Adverse Events

Form: Adverse Events (2)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:07:52
DataPoint Verified.		07 Apr 2021 20:21:12
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered '0'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	25 Feb 2021 18:30:12

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:48:59

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:07:52
DataPoint Verified.		07 Apr 2021 20:21:12
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'Not Related (NOT RELATED)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	25 Feb 2021 18:30:12

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:48:59

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:07:52
DataPoint Verified.		07 Apr 2021 20:21:12
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'Not Related (NOT RELATED)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	25 Feb 2021 18:30:12



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:48:59**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:07:52
DataPoint Verified.		07 Apr 2021 20:21:12
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	25 Feb 2021 18:30:12

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Folder: Adverse Events

Form: Adverse Events (2)

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None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:07:52
DataPoint Verified.		07 Apr 2021 20:21:12
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered '0'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	25 Feb 2021 18:30:12

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:07:52
DataPoint Verified.		07 Apr 2021 20:21:12
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'I'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	25 Feb 2021 18:30:12

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Folder: Adverse Events

Form: Adverse Events (2)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:07:52
DataPoint Verified.		07 Apr 2021 20:21:12
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered '0'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	25 Feb 2021 18:30:12

**US3032115**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:48:59**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:07:52
DataPoint Verified.		07 Apr 2021 20:21:12
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	25 Feb 2021 18:30:12

US3032115

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:48:59

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:07:52
DataPoint Verified.		07 Apr 2021 20:21:12
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered empty.	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	25 Feb 2021 18:30:12

**US3032115**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:48:59**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:07:52
DataPoint Verified.		07 Apr 2021 20:21:12
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered empty.	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	25 Feb 2021 18:30:12

US3032115

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:48:59

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:07:52
User entered '0'	System	25 Feb 2021 18:30:12



**US3032115**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:48:59**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:07:52
User entered 'I'	System	25 Feb 2021 18:30:12

**US3032115**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:48:59**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:07:52

**US3032115**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:48:59**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:07:59

US3032115

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:48:59

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:07:59
DataPoint Verified.		07 Apr 2021 20:21:12
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:21
User closed query 'Per DM CLR: Please verify if this event is a worsening of the ongoing MH conditon. If yes, please update the AE term to reflect the term 'worsening or exacerbation' and ensure grade is more than 1/Mild. Otherwise, If this is a duplicate please confirm if it meets the AE reporting criteria. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Mar 2021 12:23:53
User coded data point as SOC: Congenital, familial and genetic disorders, HLGT: Metabolic and nutritional disorders congenital, HLT: Inborn errors of lipid metabolism, PT: Type IIa hyperlipidaemia, LLT: Homozygous familial hypercholesterolemia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	31 Mar 2021 09:56:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	31 Mar 2021 09:56:37
Query 'Per DM CLR: Please verify if this event is a worsening of the ongoing MH conditon. If yes, please update the AE term to reflect the term 'worsening or exacerbation' and ensure grade is more than 1/Mild. Otherwise, If this is a duplicate please confirm if it meets the AE reporting criteria. ' answered with 'updated. Per PI still grade 1' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	29 Mar 2021 13:57:19
Data point term sent to Coder	System	29 Mar 2021 13:56:36
Coding entries removed.	Samantha Wieseler (b) (4) (b) (4)	29 Mar 2021 13:56:16
Signature has been broken.	Samantha Wieseler (b) (4) (b) (4)	29 Mar 2021 13:56:16
User entered 'Worsening of HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA' reason for change: New Information	Samantha Wieseler (b) (4) (b) (4)	29 Mar 2021 13:56:16

US3032115

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:48:59

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please verify if this event is a worsening of the ongoing MH conditon. If yes, please update the AE term to reflect the term 'worsening or exacerbation' and ensure grade is more than 1/Mild. Otherwise, If this is a duplicate please confirm if it meets the AE reporting criteria. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6) (b) (4)	29 Mar 2021 10:53:17
	Keith Vrbicky (b) (4) (b) (4)	18 Mar 2021 21:11:10
User coded data point as SOC: Congenital, familial and genetic disorders, HLGT: Metabolic and nutritional disorders congenital, HLT: Inborn errors of lipid metabolism, PT: Type IIa hyperlipidaemia, LLT: Homozygous familial hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Mar 2021 22:37:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Mar 2021 22:37:57
Data point term sent to Coder	System	16 Mar 2021 22:37:26
User entered 'homozygous familial hypercholesterolemia' reason for change: New Information	Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 22:37:11
Data point term sent to Coder	System	16 Mar 2021 22:26:18
User entered 'VPB'	Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 22:25:55

**US3032115**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:48:59**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:07:59
DataPoint Verified.		07 Apr 2021 20:21:12
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 22:25:55

US3032115

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:48:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:07:59
DataPoint Verified.		07 Apr 2021 20:21:12
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 22:25:55

US3032115

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:48:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:07:59
DataPoint Verified.		07 Apr 2021 20:21:12
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 22:25:55



**US3032115**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:48:59**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:07:59
DataPoint Verified.		07 Apr 2021 20:21:12
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered '15 Oct 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 22:25:55

**US3032115**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:48:59**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:07:59
DataPoint Verified.		07 Apr 2021 20:21:12
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 22:25:55

**US3032115**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:48:59**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:07:59
User entered empty.	System	16 Mar 2021 22:25:55

US3032115

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:48:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:07:59
DataPoint Verified.		07 Apr 2021 20:21:12
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 22:25:55

**US3032115**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:48:59**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:07:59
DataPoint Verified.		07 Apr 2021 20:21:12
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered '16 Mar 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 22:25:55

**US3032115**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:48:59**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:07:59
DataPoint Verified.		07 Apr 2021 20:21:12
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 22:25:55

**US3032115**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:48:59**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:07:59
User entered empty.	System	16 Mar 2021 22:25:55

US3032115

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:48:59

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:07:59
DataPoint Verified.		07 Apr 2021 20:21:12
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 22:25:55



US3032115

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:48:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:07:59
DataPoint Verified.		07 Apr 2021 20:21:12
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 22:25:55

**US3032115**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:48:59**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:07:59
DataPoint Verified.		07 Apr 2021 20:21:12
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 22:25:55

US3032115

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:48:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:07:59
DataPoint Verified.		07 Apr 2021 20:21:12
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 22:25:55

US3032115

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:48:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:07:59
DataPoint Verified.		07 Apr 2021 20:21:12
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 22:25:55

**US3032115**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:48:59**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:07:59
DataPoint Verified.		07 Apr 2021 20:21:12
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 22:25:55

US3032115

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:48:59

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:07:59
DataPoint Verified.		07 Apr 2021 20:21:12
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 22:25:55

**US3032115**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:48:59**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:07:59
DataPoint Verified.		07 Apr 2021 20:21:12
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 22:25:55

**US3032115**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:48:59**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:07:59
DataPoint Verified.		07 Apr 2021 20:21:12
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 22:25:55



US3032115

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:48:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:07:59
DataPoint Verified.		07 Apr 2021 20:21:12
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 22:25:55

US3032115

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:48:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:07:59
DataPoint Verified.		07 Apr 2021 20:21:12
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 22:25:55

**US3032115**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:48:59**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:07:59
DataPoint Verified.		07 Apr 2021 20:21:12
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 22:25:55

US3032115

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:48:59

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:07:59
DataPoint Verified.		07 Apr 2021 20:21:12
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'Not Related (NOT RELATED)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 22:25:55

US3032115

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:48:59

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:07:59
DataPoint Verified.		07 Apr 2021 20:21:12
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'Not Related (NOT RELATED)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 22:25:55

US3032115

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:48:59

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:07:59
DataPoint Verified.		07 Apr 2021 20:21:12
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 22:25:55

**US3032115**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:48:59**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:07:59
DataPoint Verified.		07 Apr 2021 20:21:12
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 22:25:55

US3032115

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:48:59

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:07:59
DataPoint Verified.		07 Apr 2021 20:21:12
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'l'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 22:25:55



**US3032115**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:48:59**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:07:59
DataPoint Verified.		07 Apr 2021 20:21:12
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 22:25:55

**US3032115**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:48:59**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:07:59
DataPoint Verified.		07 Apr 2021 20:21:12
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 22:25:55

**US3032115**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:48:59**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:07:59
DataPoint Verified.		07 Apr 2021 20:21:12
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 22:25:55

**US3032115**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:48:59**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:07:59
DataPoint Verified.		07 Apr 2021 20:21:12
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 22:25:55

**US3032115**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:48:59**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:07:59
User entered '0'	System	16 Mar 2021 22:25:55

**US3032115**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:48:59**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:07:59
User entered '0'	System	16 Mar 2021 22:25:55

US3032115

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:48:59

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:07:59

US3032115

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 09 Jun 2021 14:48:59**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:09:00
DataPoint Verified.		17 Dec 2020 20:10:27
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 21:02:42



US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:48:59

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: CLOPIDOGREL BISULFATE, PRODUCTSYNONYM: PLAVIX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Sep 2020 06:35:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Sep 2020 06:35:59
Data point term sent to Coder	System	15 Sep 2020 13:26:30
Coding entries removed.	Kelsey Kelley (b) (4)	15 Sep 2020 13:25:46
User entered 'PLAVIX clopidogrel' reason for change: Data Entry Error	(b) (4)	
	Kelsey Kelley (b) (4)	15 Sep 2020 13:25:46
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: CLOPIDOGREL BISULFATE, PRODUCTSYNONYM: PLAVIX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Aug 2020 21:04:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Aug 2020 21:04:58
Data point term sent to Coder	System	06 Aug 2020 21:04:40
User entered 'plavix'	Kelsey Kelley (b) (4)	06 Aug 2020 21:04:07

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:48:59

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 21:04:07

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:48:59

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'Medical history: aortic aneurism'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 21:04:07

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:48:59

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered '300'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 21:04:07

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:48:59

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'mg (mg)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 21:04:07

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:48:59

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 21:04:07
	(b) (4)	

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:48:59

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'once daily (QD)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 21:04:07

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:48:59

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 21:04:07
	(b) (4)	



US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:48:59

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'Oral (ORAL)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 21:04:07
	(b) (4)	

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:48:59

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 21:04:07
	(b) (4)	

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:48:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	12 Aug 2020 14:15:01
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	06 Aug 2020 21:04:07
User entered 'un UNK 2013'	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 21:04:07

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:48:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 21:04:07

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:48:59

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User closed query 'Per DM CLR: Please note, the MH condition of Aortic Aneurysm is already resolved. However, this medication is still ongoing. Please reconcile dates and update if appropriate. Otherwise, clarify continued use after resolution of the MH condition.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Sep 2020 06:47:26
Query 'Per DM CLR: Please note, the MH condition of Aortic Aneurysm is already resolved. However, this medication is still ongoing. Please reconcile dates and update if appropriate. Otherwise, clarify continued use after resolution of the MH condition.' answered with 'subject had aneurysm, plavix is a med that helps resolve aneurysm as well as prevent further issues therefore ongoing. ' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	29 Sep 2020 21:40:34
User opened query 'Per DM CLR: Please note, the MH condition of Aortic Aneurysm is already resolved. However, this medication is still ongoing. Please reconcile dates and update if appropriate. Otherwise, clarify continued use after resolution of the MH condition.' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 14:28:28
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 21:04:07

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:48:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 21:04:07

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:48:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 21:04:07

**US3032115**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:48:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 21:04:07



**US3032115**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:48:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 21:04:07

**US3032115**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:48:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Aug 2020 21:04:07

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:48:59

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Nov 2020 16:47:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Nov 2020 16:47:48
Data point term sent to Coder	System	18 Nov 2020 16:47:36
Coding entries removed.	Linden DeBoer (b) (4)	18 Nov 2020 16:47:22
User signature succeeded.	(b) (4)	
	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Aug 2020 17:35:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Aug 2020 17:35:25
Data point term sent to Coder	System	06 Aug 2020 21:05:41
User entered 'omeprazole'	Kelsey Kelley (b) (4)	06 Aug 2020 21:05:11

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:48:59

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 21:05:11

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:48:59

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:24
Signature has been broken.	Linden DeBoer (b) (4)	18 Nov 2020 16:47:22
User entered 'MEDICAL HISTORY: Acid Reflux'	Linden DeBoer (b) (4)	18 Nov 2020 16:47:22
reason for change: Data Entry Error	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'Medical history: gastroesophageal reflux disease'	Kelsey Kelley (b) (4)	06 Aug 2020 21:05:11

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:48:59

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered '40'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 21:05:11

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:48:59

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'mg (mg)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 21:05:11

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:48:59

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 21:05:11
	(b) (4)	



US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:48:59

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'once daily (QD)'	Kelsey Kelley (b) (4)	06 Aug 2020 21:05:11

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:48:59

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 21:05:11

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:48:59

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'Oral (ORAL)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 21:05:11

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:48:59

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 21:05:11

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:48:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	12 Aug 2020 14:15:14
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	06 Aug 2020 21:05:11
User entered 'un UNK 2010'	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 21:05:11

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:48:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 21:05:11

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:48:59

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 21:05:11

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:48:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 21:05:11
	(b) (4)	



US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:48:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 21:05:11

**US3032115**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:48:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 21:05:11

**US3032115**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:48:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 21:05:11

**US3032115**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:48:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Aug 2020 21:05:11

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:48:59

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Aug 2020 18:26:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Aug 2020 18:26:16
Data point term sent to Coder	System	06 Aug 2020 21:06:44
User entered 'tramadol'	Kelsey Kelley (b) (4)	06 Aug 2020 21:05:53

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:48:59

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 21:05:53

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:48:59

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'Medical history: lower lumbar pain'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 21:05:53

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:48:59

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered '50'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 21:05:53



US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:48:59

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'mg (mg)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 21:05:53

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:48:59

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 21:05:53
	(b) (4)	

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:48:59

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'once daily (QD)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 21:05:53
	(b) (4)	

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:48:59

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 21:05:53
	(b) (4)	

**US3032115**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:48:59**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'Oral (ORAL)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 21:05:53

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:48:59

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 21:05:53

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:48:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:24
Signature has been broken.	Linden DeBoer (b) (4)	18 Nov 2020 16:47:44
User entered '05 Aug 2019' reason for change: Data Entry Error	Linden DeBoer (b) (4)	18 Nov 2020 16:47:44
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Aug 2020 23:09:55
User entered '05 Aug 2020' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	13 Aug 2020 23:09:55
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	06 Aug 2020 21:05:53
User entered '05 Aug 202' (non-conformant).	Kelsey Kelley (b) (4)	06 Aug 2020 21:05:53

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:48:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 21:05:53



US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:48:59

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:29:16
User closed query 'Per DM CLR: The corresponding MH stop date is 05Aug2019, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or MH as appropriate. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 05:59:26
Query 'Per DM CLR: The corresponding MH stop date is 05Aug2019, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or MH as appropriate. Otherwise, provide clarification for continued use of medication. ' answered with 'Data updated, lower lumbar pain is actually ongoing so this medication is as well' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	22 Dec 2020 21:59:33
DataPoint Un-verified.	(b) (4), (b) (6)	17 Dec 2020 20:04:08
DataPoint Verified.		17 Dec 2020 20:03:48
User opened query 'Per DM CLR: The corresponding MH stop date is 05Aug2019, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or MH as appropriate. Otherwise, provide clarification for continued use of medication. ' (Site from DM).		09 Dec 2020 05:53:46
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 21:50:34
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 21:05:53

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:48:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 21:05:53

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:48:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 21:05:53

**US3032115**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:48:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 21:05:53

**US3032115**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:48:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 21:05:53

**US3032115**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:48:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Aug 2020 21:05:53

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:48:59

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Aug 2020 21:09:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Aug 2020 21:09:02
Data point term sent to Coder User entered 'losartan'	System Kelsey Kelley (b) (4)	06 Aug 2020 21:07:44 06 Aug 2020 21:06:52

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:48:59

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 21:06:52



US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:48:59

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'Medical history: hypertension'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 21:06:52

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:48:59

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per the source the dosage is 50mg please update' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:30:08
		02 Feb 2021 20:12:24
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:23
	(b) (4)	
Query 'Per the source the dosage is 50mg please update' answered with 'updated ' (Site from CRA). Signature has been broken.	Kelsey Kelley (b) (4)	22 Dec 2020 21:51:45
	(b) (4)	
	Kelsey Kelley (b) (4)	22 Dec 2020 21:51:28
	(b) (4)	
User entered '50' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	22 Dec 2020 21:51:28
	(b) (4)	
User opened query 'Per the source the dosage is 50mg please update' (Site from CRA). DataPoint Un-verified.	(b) (4), (b) (6)	17 Dec 2020 20:07:56
		17 Dec 2020 20:07:20
DataPoint Verified.		17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
	(b) (4)	
User entered '80'	Kelsey Kelley (b) (4)	06 Aug 2020 21:06:52
	(b) (4)	

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:48:59

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'mg (mg)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 21:06:52

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:48:59

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 21:06:52
	(b) (4)	

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:48:59

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'once daily (QD)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 21:06:52
	(b) (4)	

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:48:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 21:06:52
	(b) (4)	

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:48:59

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'Oral (ORAL)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 21:06:52

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:48:59

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 21:06:52



US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:48:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	12 Aug 2020 14:15:36
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	06 Aug 2020 21:06:52
User entered 'un UNK 2013'	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 21:06:52

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:48:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 21:06:52

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:48:59

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 21:06:52

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:48:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 21:06:52
	(b) (4)	

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:48:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 21:06:52

**US3032115**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:48:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 21:06:52

**US3032115**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:48:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 21:06:52

**US3032115**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:48:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Aug 2020 21:06:52



US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:48:59

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, NON-SELECTIVE, PRODUCT: SOTALOL HYDROCHLORIDE, PRODUCTSYNONYM: BETAPACE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Aug 2020 21:11:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Aug 2020 21:11:03
Data point term sent to Coder	System	06 Aug 2020 21:09:47
Data point term sent to Coder	System	06 Aug 2020 21:08:47
User entered 'betapace'	Kelsey Kelley (b) (4)	06 Aug 2020 21:08:16

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:48:59

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 21:08:16

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:48:59

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Aug 2020 21:08:50
User entered 'aeortic aneurism' reason for change:	Kelsey Kelley (b) (4)	06 Aug 2020 21:08:50
Data Entry Error	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Aug 2020 21:08:16
User entered empty.	Kelsey Kelley (b) (4)	06 Aug 2020 21:08:16
	(b) (4)	

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:48:59

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered '80'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 21:08:16

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:48:59

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'mg (mg)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 21:08:16

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:48:59

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 21:08:16
	(b) (4)	

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:48:59

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'once daily (QD)'	Kelsey Kelley (b) (4)	06 Aug 2020 21:08:16

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:48:59

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 21:08:16
	(b) (4)	



US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:48:59

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'Oral (ORAL)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 21:08:16
	(b) (4)	

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:48:59

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 21:08:16

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:48:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	12 Aug 2020 14:15:46
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	06 Aug 2020 21:08:16
User entered 'un UNK 2013'	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 21:08:16

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:48:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 21:08:16

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:48:59

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 21:08:16

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:48:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 21:08:16
	(b) (4)	

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:48:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 21:08:16

**US3032115**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:48:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 21:08:16



**US3032115**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:48:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 21:08:16

**US3032115**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:48:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Aug 2020 21:08:16

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:48:59

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: ALPRAZOLAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Sep 2020 13:27:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Sep 2020 13:27:50
Data point term sent to Coder	System	15 Sep 2020 13:27:31
User entered 'alprazolam'	Kelsey Kelley (b) (4)	15 Sep 2020 13:26:49

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:48:59

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	15 Sep 2020 13:26:49
	(b) (4)	

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:48:59

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'medical history: anxiety'	Kelsey Kelley (b) (4)	15 Sep 2020 13:26:49

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:48:59

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered '.5'	(b) (4) Kelsey Kelley (b) (4)	15 Sep 2020 13:26:49

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:48:59

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'mg (mg)'	(b) (4) Kelsey Kelley (b) (4)	15 Sep 2020 13:26:49
	(b) (4)	

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:48:59

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	15 Sep 2020 13:26:49
	(b) (4)	



US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:48:59

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'twice daily (BID)'	Kelsey Kelley (b) (4)	15 Sep 2020 13:26:49

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:48:59

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	15 Sep 2020 13:26:49
	(b) (4)	

**US3032115**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:48:59**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'Oral (ORAL)'	(b) (4) Kelsey Kelley (b) (4)	15 Sep 2020 13:26:49

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:48:59

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	15 Sep 2020 13:26:49
	(b) (4)	

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:48:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'un UNK 2012'	(b) (4) Kelsey Kelley (b) (4)	15 Sep 2020 13:26:49

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:48:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered '0'	Kelsey Kelley (b) (4)	15 Sep 2020 13:26:49

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:48:59

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	15 Sep 2020 13:26:49

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:48:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	15 Sep 2020 13:26:49
	(b) (4)	



US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:48:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	15 Sep 2020 13:26:49

**US3032115**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:48:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	15 Sep 2020 13:26:49

US3032115

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:48:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 13:26:49

**US3032115**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:48:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Sep 2020 13:26:49

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:48:59

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Sep 2020 13:27:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Sep 2020 13:27:50
Data point term sent to Coder	System	15 Sep 2020 13:27:31
User entered 'amlodipine'	Kelsey Kelley (b) (4)	15 Sep 2020 13:27:19

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:48:59

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	15 Sep 2020 13:27:19

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:48:59

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'medical history: hypertension'	Kelsey Kelley (b) (4)	15 Sep 2020 13:27:19

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:48:59

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered '5'	Kelsey Kelley (b) (4)	15 Sep 2020 13:27:19



US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:48:59

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'mg (mg)'	Kelsey Kelley (b) (4)	15 Sep 2020 13:27:19

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:48:59

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	15 Sep 2020 13:27:19
	(b) (4)	

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:48:59

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'once daily (QD)'	Kelsey Kelley (b) (4)	15 Sep 2020 13:27:19

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:48:59

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	15 Sep 2020 13:27:19
	(b) (4)	

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:48:59

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'Oral (ORAL)'	(b) (4) Kelsey Kelley (b) (4)	15 Sep 2020 13:27:19
	(b) (4)	

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:48:59

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	15 Sep 2020 13:27:19
	(b) (4)	

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:48:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User closed query 'Per DM CLR: Please review the start date of this medication as it was noted as prior to the start date of the corresponding MH record. Please reconcile and update applicable details as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Sep 2020 06:47:55
Query 'Per DM CLR: Please review the start date of this medication as it was noted as prior to the start date of the corresponding MH record. Please reconcile and update applicable details as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	29 Sep 2020 21:41:24
User entered 'UN UNK 2013' reason for change: Data Entry Error	Samantha Wieseler (b) (4) (b) (4)	29 Sep 2020 21:41:16
User opened query 'Per DM CLR: Please review the start date of this medication as it was noted as prior to the start date of the corresponding MH record. Please reconcile and update applicable details as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 14:27:14
User entered 'un UNK 2012'	Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 13:27:19

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:48:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered '0'	Kelsey Kelley (b) (4)	15 Sep 2020 13:27:19



US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:48:59

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	15 Sep 2020 13:27:19
	(b) (4)	

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:48:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	15 Sep 2020 13:27:19
	(b) (4)	

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:48:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	15 Sep 2020 13:27:19

**US3032115**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:48:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 13:27:19

**US3032115**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:48:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 13:27:19

**US3032115**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:48:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Sep 2020 13:27:19

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:48:59

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
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)	15 Sep 2020 13:29:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Sep 2020 13:29:49
Data point term sent to Coder	System	15 Sep 2020 13:28:34
User entered 'aspirin'	Kelsey Kelley (b) (4)	15 Sep 2020 13:27:57

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:48:59

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	15 Sep 2020 13:27:57



US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:48:59

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'cardiac prophylaxis'	Kelsey Kelley (b) (4)	15 Sep 2020 13:27:57

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:48:59

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered '81'	(b) (4) Kelsey Kelley (b) (4)	15 Sep 2020 13:27:57

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:48:59

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'mg (mg)'	(b) (4) Kelsey Kelley (b) (4)	15 Sep 2020 13:27:57
	(b) (4)	

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:48:59

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	15 Sep 2020 13:27:57
	(b) (4)	

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:48:59

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'once daily (QD)'	Kelsey Kelley (b) (4)	15 Sep 2020 13:27:57

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:48:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	15 Sep 2020 13:27:57
	(b) (4)	

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:48:59

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'Oral (ORAL)'	(b) (4) Kelsey Kelley (b) (4)	15 Sep 2020 13:27:57

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:48:59

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	15 Sep 2020 13:27:57
	(b) (4)	



US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:48:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'un UNK 2004'	(b) (4) Kelsey Kelley (b) (4)	15 Sep 2020 13:27:57

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:48:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	15 Sep 2020 13:27:57
	(b) (4)	

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:48:59

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	15 Sep 2020 13:27:57
	(b) (4)	

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:48:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	15 Sep 2020 13:27:57
	(b) (4)	

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:48:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	15 Sep 2020 13:27:57

**US3032115**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:48:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 13:27:57

**US3032115**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:48:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 13:27:57

**US3032115**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:48:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Sep 2020 13:27:57



US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:48:59

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: VASODILATORS USED IN CARDIAC DISEASES, ATC: ORGANIC NITRATES, PRODUCT: ISOSORBIDE MONONITRATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Sep 2020 13:37:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Sep 2020 13:37:40
Data point term sent to Coder	System	15 Sep 2020 13:31:39
User entered 'isosorbide mononitrate er'	Kelsey Kelley (b) (4)	15 Sep 2020 13:30:44

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:48:59

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	15 Sep 2020 13:30:44
	(b) (4)	

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:48:59

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'medical history: aortic aneurysm'	(b) (4) Kelsey Kelley (b) (4)	15 Sep 2020 13:30:44

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:48:59

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered '60'	Kelsey Kelley (b) (4)	15 Sep 2020 13:30:44

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:48:59

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'mg (mg)'	(b) (4) Kelsey Kelley (b) (4)	15 Sep 2020 13:30:44

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:48:59

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	15 Sep 2020 13:30:44
	(b) (4)	

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:48:59

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'once daily (QD)'	Kelsey Kelley (b) (4)	15 Sep 2020 13:30:44

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:48:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	15 Sep 2020 13:30:44
	(b) (4)	



US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:48:59

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'Oral (ORAL)'	Kelsey Kelley (b) (4)	15 Sep 2020 13:30:44

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:48:59

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	15 Sep 2020 13:30:44
	(b) (4)	

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:48:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'un UNK 2013'	Kelsey Kelley (b) (4)	15 Sep 2020 13:30:44

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:48:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered '0'	Kelsey Kelley (b) (4)	15 Sep 2020 13:30:44

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:48:59

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User closed query 'Per DM CLR: Please note, the MH condition of Aortic Aneurysm is already resolved. However, this medication is still ongoing. Please reconcile dates and update if appropriate. Otherwise, clarify continued use after resolution of the MH condition.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Sep 2020 06:48:30
Query 'Per DM CLR: Please note, the MH condition of Aortic Aneurysm is already resolved. However, this medication is still ongoing. Please reconcile dates and update if appropriate. Otherwise, clarify continued use after resolution of the MH condition.' answered with 'helped resolve aneurysm and helps prevent further issue' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	29 Sep 2020 21:42:12
User opened query 'Per DM CLR: Please note, the MH condition of Aortic Aneurysm is already resolved. However, this medication is still ongoing. Please reconcile dates and update if appropriate. Otherwise, clarify continued use after resolution of the MH condition.' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 14:27:57
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 13:30:44

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:48:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	15 Sep 2020 13:30:44
	(b) (4)	

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:48:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	15 Sep 2020 13:30:44

**US3032115**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:48:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 13:30:44



**US3032115**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:48:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 13:30:44

**US3032115**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:48:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Sep 2020 13:30:44

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:48:59

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: PRAVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Sep 2020 13:32:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Sep 2020 13:32:49
Data point term sent to Coder	System	15 Sep 2020 13:31:39
User entered 'pravastatin'	Kelsey Kelley (b) (4)	15 Sep 2020 13:31:10

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:48:59

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	15 Sep 2020 13:31:10

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:48:59

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User closed query 'Per DM CLR: Please review Indication and please note that there is no corresponding MH record that match this condition. Please reconcile and update applicable details as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Sep 2020 06:51:50
Query 'Per DM CLR: Please review Indication and please note that there is no corresponding MH record that match this condition. Please reconcile and update applicable details as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	29 Sep 2020 21:43:15
User opened query 'Per DM CLR: Please review Indication and please note that there is no corresponding MH record that match this condition. Please reconcile and update applicable details as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 14:28:57
User entered 'medical history: hypercholesterolemia'	Kelsey Kelley (b) (4) (b) (4)	15 Sep 2020 13:31:10

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:48:59

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered '20'	Kelsey Kelley (b) (4)	15 Sep 2020 13:31:10

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:48:59

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'mg (mg)'	Kelsey Kelley (b) (4)	15 Sep 2020 13:31:10

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:48:59

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	15 Sep 2020 13:31:10
	(b) (4)	



US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:48:59

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'once daily (QD)'	Kelsey Kelley (b) (4)	15 Sep 2020 13:31:10

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:48:59

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	15 Sep 2020 13:31:10
	(b) (4)	

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:48:59

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'Oral (ORAL)'	Kelsey Kelley (b) (4)	15 Sep 2020 13:31:10

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:48:59

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	15 Sep 2020 13:31:10
	(b) (4)	

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:48:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'un UNK 2012'	(b) (4) Kelsey Kelley (b) (4)	15 Sep 2020 13:31:10

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:48:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	15 Sep 2020 13:31:10

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:48:59

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	15 Sep 2020 13:31:10

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:48:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	15 Sep 2020 13:31:10
	(b) (4)	



US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:48:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:34
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	15 Sep 2020 13:31:10

**US3032115**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:48:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 13:31:10

**US3032115**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:48:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 13:31:10

**US3032115**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:48:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Sep 2020 13:31:10

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:48:59

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:53
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: DEXAMETHASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Feb 2021 09:20:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Feb 2021 09:20:58
Data point term sent to Coder	System	15 Feb 2021 17:59:08
Coding entries removed.	Samantha Wieseler (b) (4)	15 Feb 2021 17:58:57
User signature succeeded.	(b) (4)	
	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: DEXAMETHASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Dec 2020 07:12:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Dec 2020 07:12:44
Data point term sent to Coder	System	09 Dec 2020 20:55:31
User entered 'dexamethasone'	Kelsey Kelley (b) (4)	09 Dec 2020 20:55:13
	(b) (4)	

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:48:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:53
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 20:03:48
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 20:55:13

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:48:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:31:22
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:23:36
User closed query 'Per CDM CLR re-query: Response noted, since it was taken for Bilateral Pneumonia , kindly update the same in the indication field else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Feb 2021 07:18:05
Query 'Per CDM CLR re-query: Response noted, since it was taken for Bilateral Pneumonia , kindly update the same in the indication field else clarify.' answered with 'updated' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	15 Feb 2021 17:59:03
DataPoint Un-verified.	Samantha Wieseler (b) (4) (b) (4)	15 Feb 2021 17:58:57
Signature has been broken.	Samantha Wieseler (b) (4) (b) (4)	15 Feb 2021 17:58:57
User entered 'BiLateral Pneumonia' reason for change: Data Entry Error	Samantha Wieseler (b) (4) (b) (4)	15 Feb 2021 17:58:57
User opened query 'Per CDM CLR re-query: Response noted, since it was taken for Bilateral Pneumonia , kindly update the same in the indication field else clarify.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 17:41:32
User closed query 'Per CDM CLR re-query: Response noted; however AE has not been updated. Kindly review and update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 17:41:32
Query 'Per CDM CLR re-query: Response noted; however AE has not been updated. Kindly review and update accordingly. Thank you.' answered with 'AE is Bilateral Pneumonia. They had been seen at an earlier date for suspected covid and was put on dexamethasone for said suspicion ' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	11 Feb 2021 20:10:24
User opened query 'Per CDM CLR re-query: Response noted; however AE has not been updated. Kindly review and update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 17:07:10

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:48:59

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 17:05:20
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'will update accordingly' (Site from DM).	Samantha Wieseler (b) (4)	01 Feb 2021 20:08:24
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 09:23:22
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 20:03:48
User entered 'suspected covid-19'	Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 20:55:13



US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:48:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:53
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 20:03:48
User entered '6'	Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 20:55:13

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:48:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:53
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 20:03:48
User entered 'mg (mg)'	Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 20:55:13

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:48:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:53
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 20:03:48
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 20:55:13

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:48:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:53
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 20:03:48
User entered 'once daily (QD)'	Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 20:55:13

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:48:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:53
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 20:03:48
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 20:55:13

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:48:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:53
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 20:03:48
User entered 'Oral (ORAL)'	Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 20:55:13

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:48:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:53
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 20:03:48
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 20:55:13

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:48:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:53
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 20:03:48
User entered '09 Dec 2020'	Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 20:55:13



US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:48:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:53
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 20:03:48
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 20:55:13

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:48:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:31:22
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:23
DataPoint Un-verified.	(b) (4)	
	Kelsey Kelley (b) (4)	21 Dec 2020 14:53:07
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Kelsey Kelley (b) (4)	21 Dec 2020 14:53:07
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	09 Dec 2020 20:55:13
	(b) (4)	

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:48:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:31:22
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:23
DataPoint Un-verified.	(b) (4) Kelsey Kelley (b) (4)	21 Dec 2020 14:53:07
User entered '18 Dec 2020' reason for change: Data Entry Error	(b) (4) Kelsey Kelley (b) (4)	21 Dec 2020 14:53:07
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 20:55:13

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:48:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:53
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 20:03:48
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 20:55:13

**US3032115**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 14:48:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:53
User entered '1'	System	09 Dec 2020 20:55:13

**US3032115**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 14:48:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:53
User entered '1'	System	09 Dec 2020 20:55:13

**US3032115**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 14:48:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:53
User entered '804 (804)'	System	09 Dec 2020 20:55:13

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:48:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:49
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS, ATC: OTHER COUGH SUPPRESSANTS, PRODUCT: BENZONATATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 04:58:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 04:58:17
Data point term sent to Coder	System	05 Mar 2021 20:17:59
Coding entries removed.	Kelsey Kelley (b) (4) (b) (4)	05 Mar 2021 20:17:36
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	23 Dec 2020 15:53:23
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS, ATC: OTHER COUGH SUPPRESSANTS, PRODUCT: BENZONATATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Dec 2020 18:54:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Dec 2020 18:54:28
Data point term sent to Coder	System	09 Dec 2020 20:56:32
User entered 'benzonatate'	Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 20:56:23



US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:48:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:49
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 20:03:48
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 20:56:23

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:48:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:49
DataPoint Verified.		14 Apr 2021 20:09:10
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:21:18
DataPoint Un-verified.	(b) (4)	
	Kelsey Kelley (b) (4)	05 Mar 2021 20:17:36
	(b) (4)	
Signature has been broken.	Kelsey Kelley (b) (4)	05 Mar 2021 20:17:36
	(b) (4)	
User entered 'bilateral pneumonia' reason for change: New Information	Kelsey Kelley (b) (4)	05 Mar 2021 20:17:36
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User entered 'suspected covid-19'	Kelsey Kelley (b) (4)	09 Dec 2020 20:56:23
	(b) (4)	

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:48:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:49
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 20:03:48
User entered '100'	Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 20:56:23

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:48:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:49
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 20:03:48
User entered 'mg (mg)'	Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 20:56:23

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:48:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:49
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 20:03:48
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 20:56:23

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:48:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:49
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 20:03:48
User entered 'as needed (PRN)'	Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 20:56:23

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:48:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:49
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 20:03:48
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 20:56:23

**US3032115**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:48:59**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:49
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 20:03:48
User entered 'Oral (ORAL)'	Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 20:56:23



US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:48:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:49
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 20:03:48
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 20:56:23

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:48:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:49
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 20:03:48
User entered '9 Dec 2020'	Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 20:56:23

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:48:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:49
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 20:03:48
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 20:56:23

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:48:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:49
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:33:46
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
DataPoint Un-verified.	(b) (4)	
	Kelsey Kelley (b) (4)	09 Feb 2021 02:14:07
Signature has been broken.	(b) (4)	
	Kelsey Kelley (b) (4)	09 Feb 2021 02:14:07
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Kelsey Kelley (b) (4)	09 Feb 2021 02:14:07
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User entered 'Yes (Y)'	(b) (4)	
	Kelsey Kelley (b) (4)	09 Dec 2020 20:56:23
	(b) (4)	

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:48:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:49
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:20:03
User closed query 'Per the source the end date of this medication was 21DEC20 please refer to the source and update' (Site from CRA).	(b) (4) (b) (4), (b) (6)	13 Apr 2021 14:14:54
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:14:43
Query 'Per the source the end date of this medication was 21DEC20 please refer to the source and update' answered with 'updated' (Site from CRA).	Samantha Wieseler (b) (4)	13 Apr 2021 13:42:28
Signature has been broken.	(b) (4)	
User entered '21 Dec 2020' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	13 Apr 2021 13:42:13
User opened query 'Per the source the end date of this medication was 21DEC20 please refer to the source and update' (Site from CRA).	(b) (4)	
User signature succeeded.	(b) (4), (b) (6)	07 Apr 2021 20:33:18
User closed query 'Per DM CLR: The corresponding AE has resolved on 20 DEC 2020, however the medication stop date was 21 DEC 2020. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication.	Keith Vrbicky (b) (4)	25 Mar 2021 14:17:35
' (Site from DM).	(b) (4)	
Query 'Per DM CLR: The corresponding AE has resolved on 20 DEC 2020, however the medication stop date was 21 DEC 2020. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication.	(b) (4), (b) (6)	24 Mar 2021 01:05:31
' answered with 'updated' (Site from DM).		
Signature has been broken.	Samantha Wieseler (b) (4)	22 Mar 2021 18:08:07
User entered '20 Dec 2020' reason for change: Data Entry Error	(b) (4)	
	Samantha Wieseler (b) (4)	22 Mar 2021 18:07:54
	(b) (4)	

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:48:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: The corresponding AE has resolved on 20 DEC 2020, however the medication stop date was 21 DEC 2020. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6) (b) (4)	17 Mar 2021 06:17:19
DataPoint Un-verified.	Keith Vrbicky (b) (4) (b) (4)	12 Feb 2021 19:54:32
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 02:14:07
User entered '21 Dec 2020' reason for change: Data Entry Error User signature succeeded.	Kelsey Kelley (b) (4) (b) (4) Keith Vrbicky (b) (4) (b) (4)	09 Feb 2021 02:14:07
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 20:56:23

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:48:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:49
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 20:03:48
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 20:56:23

**US3032115**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:48:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:49
User entered empty.	System	09 Dec 2020 20:56:23



US3032115

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:48:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:49
User entered empty.	System	09 Dec 2020 20:56:23

US3032115

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:48:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:49
User entered empty.	System	09 Dec 2020 20:56:23

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:48:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:46
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)	08 Mar 2021 04:32:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Mar 2021 04:32:58
Data point term sent to Coder	System	05 Mar 2021 20:19:06
Coding entries removed.	Kelsey Kelley (b) (4)	05 Mar 2021 20:18:55
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)	02 Feb 2021 07:33:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Feb 2021 07:33:45
Data point term sent to Coder	System	01 Feb 2021 20:09:39
Coding entries removed.	Samantha Wieseler (b) (4)	01 Feb 2021 20:08:47
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:23
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:48:59

Name of Medication

Audit	User		Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS FOR SYSTEMIC USE, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	(b) (4)	10 Dec 2020 18:38:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	(b) (4)	10 Dec 2020 18:38:01
Data point term sent to Coder	System		09 Dec 2020 20:58:33
User entered 'albuterol'	Kelsey Kelley (b) (4)	(b) (4)	09 Dec 2020 20:57:57

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:48:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:46
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 20:03:48
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 20:57:57

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:48:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:46
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:34:15
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:21:18
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Mar 2021 19:33:50
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' answered with 'updated' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	05 Mar 2021 20:18:59
DataPoint Un-verified.	Kelsey Kelley (b) (4) (b) (4)	05 Mar 2021 20:18:55
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	05 Mar 2021 20:18:55
User entered 'bilateral pneumonia' reason for change: New Information	Kelsey Kelley (b) (4) (b) (4)	05 Mar 2021 20:18:55
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 13:48:57
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	23 Dec 2020 15:53:23
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User entered 'suspected covid-19'	Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 20:57:57

**US3032115**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:48:59**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:46
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 20:03:48
User entered '90'	Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 20:57:57

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:48:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:46
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 20:03:48
User entered 'ug (ug)'	Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 20:57:57



US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:48:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:46
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 20:03:48
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 20:57:57

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:48:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:46
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 20:03:48
User entered 'as needed (PRN)'	Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 20:57:57

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:48:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:46
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 20:03:48
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 20:57:57

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:48:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:46
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:34:20
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:39:23
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 15:04:47
DataPoint Un-verified.	Samantha Wieseler (b) (4)	01 Feb 2021 20:08:53
Signature has been broken.	(b) (4)	
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	01 Feb 2021 20:08:47
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).	(b) (4)	
User signature succeeded.	Samantha Wieseler (b) (4)	01 Feb 2021 20:08:47
DataPoint Verified.	(b) (4)	
User entered 'Oral (ORAL)'	Samantha Wieseler (b) (4)	01 Feb 2021 20:08:47
	(b) (4)	
	(b) (4), (b) (6)	29 Jan 2021 09:24:00
	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:23
	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 20:03:48
	Kelsey Kelley (b) (4)	09 Dec 2020 20:57:57
	(b) (4)	

**US3032115**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:48:59**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:46
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 20:03:48
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 20:57:57

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:48:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:46
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 20:03:48
User entered '09 Dec 2020'	Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 20:57:57

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:48:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:46
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 20:03:48
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 20:57:57

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:48:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:46
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:34:25
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
DataPoint Un-verified.	(b) (4)	
	Kelsey Kelley (b) (4)	09 Feb 2021 02:14:26
Signature has been broken.	(b) (4)	
	Kelsey Kelley (b) (4)	09 Feb 2021 02:14:26
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Kelsey Kelley (b) (4)	09 Feb 2021 02:14:26
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User entered 'Yes (Y)'	(b) (4)	
	Kelsey Kelley (b) (4)	09 Dec 2020 20:57:57
	(b) (4)	



US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:48:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:46
DataPoint Verified.		07 Apr 2021 20:34:30
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
DataPoint Un-verified.	(b) (4)	
	Kelsey Kelley (b) (4)	09 Feb 2021 02:14:26
Signature has been broken.	(b) (4)	
	Kelsey Kelley (b) (4)	09 Feb 2021 02:14:26
User entered '24 Dec 2020' reason for change: Data Entry Error	(b) (4)	
	Kelsey Kelley (b) (4)	09 Feb 2021 02:14:26
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User entered empty.		
	Kelsey Kelley (b) (4)	09 Dec 2020 20:57:57
	(b) (4)	

**US3032115**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:48:59**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:46
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 20:03:48
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	09 Dec 2020 20:57:57

**US3032115**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:48:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:46
User entered empty.	System	09 Dec 2020 20:57:57

US3032115

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:48:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:46
User entered empty.	System	09 Dec 2020 20:57:57

US3032115

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:48:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:46
User entered empty.	System	09 Dec 2020 20:57:57

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:48:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:42
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:23
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: LEVOFLOXACIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 00:49:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 00:49:49
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 20:03:48
Data point term sent to Coder	System	16 Dec 2020 16:37:12
User entered 'levofloxacin'	Kelsey Kelley (b) (4)	16 Dec 2020 16:36:38

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:48:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:42
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 20:03:48
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	16 Dec 2020 16:36:38

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:48:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:42
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 20:03:48
User entered 'bilateral pneumonia'	Kelsey Kelley (b) (4) (b) (4)	16 Dec 2020 16:36:38



US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:48:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:42
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 20:03:48
User entered '750'	Kelsey Kelley (b) (4) (b) (4)	16 Dec 2020 16:36:38

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:48:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:42
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 20:03:48
User entered 'mg (mg)'	Kelsey Kelley (b) (4) (b) (4)	16 Dec 2020 16:36:38

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:48:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:42
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 20:03:48
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	16 Dec 2020 16:36:38

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:48:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:42
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 20:03:48
User entered 'once daily (QD)'	Kelsey Kelley (b) (4) (b) (4)	16 Dec 2020 16:36:38

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:48:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:42
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 20:03:48
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	16 Dec 2020 16:36:38

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:48:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:42
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 20:03:48
User entered 'Oral (ORAL)'	Kelsey Kelley (b) (4) (b) (4)	16 Dec 2020 16:36:38

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:48:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:42
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 20:03:48
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	16 Dec 2020 16:36:38

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:48:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:42
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 20:03:48
User entered '14 Dec 2020'	Kelsey Kelley (b) (4) (b) (4)	16 Dec 2020 16:36:38



US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:48:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:42
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 20:03:48
User entered '0'	Kelsey Kelley (b) (4) (b) (4)	16 Dec 2020 16:36:38

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:48:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:42
DataPoint Verified.		07 Apr 2021 20:36:36
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:23
DataPoint Un-verified.	(b) (4)	
	Kelsey Kelley (b) (4)	21 Dec 2020 14:52:51
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Kelsey Kelley (b) (4)	21 Dec 2020 14:52:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	16 Dec 2020 16:36:38
	(b) (4)	

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:48:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:42
DataPoint Verified.		07 Apr 2021 20:36:36
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:23
DataPoint Un-verified.	(b) (4)	
	Kelsey Kelley (b) (4)	21 Dec 2020 14:52:51
User entered '21 Dec 2020' reason for change: Data Entry Error	(b) (4)	
	Kelsey Kelley (b) (4)	21 Dec 2020 14:52:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 20:03:48
User entered empty.	Kelsey Kelley (b) (4)	16 Dec 2020 16:36:38
	(b) (4)	

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:48:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:42
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 20:03:48
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	16 Dec 2020 16:36:38

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:48:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:42
User entered '1'	System	16 Dec 2020 16:36:38

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:48:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:42
User entered '1'	System	16 Dec 2020 16:36:38

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:48:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:42
User entered '804 (804)'	System	16 Dec 2020 16:36:38

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:48:59

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:37
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: NORMAL SALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Apr 2021 17:49:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Apr 2021 17:49:57
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:39:41
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: NORMAL SALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Mar 2021 10:28:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Mar 2021 10:28:29
Data point term sent to Coder	System	05 Mar 2021 20:25:11
Coding entries removed.	Kelsey Kelley (b) (4)	05 Mar 2021 20:24:14
User signature succeeded.	(b) (4)	
	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: NORMAL SALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Feb 2021 10:47:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Feb 2021 10:47:44



US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:48:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	09 Feb 2021 02:05:21
User entered 'Normal Saline'	Kelsey Kelley (b) (4)	09 Feb 2021 02:04:55
	(b) (4)	

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:48:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:39:41
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 02:04:55

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:48:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:37
DataPoint Verified.		07 Apr 2021 20:39:41
Query 'Per the source this medication was for the indication of Bilateral Pneumonia please clarify, refer to the source and update ' canceled (Site from CRA).		07 Apr 2021 20:38:53
User opened query 'Per the source this medication was for the indication of Bilateral Pneumonia please clarify, refer to the source and update ' (Site from CRA).		07 Apr 2021 20:38:36
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:21:18
Signature has been broken.	(b) (4)	
	Kelsey Kelley (b) (4)	05 Mar 2021 20:24:14
	(b) (4)	
User entered 'SEPSIS' reason for change: New Information	Kelsey Kelley (b) (4)	05 Mar 2021 20:24:14
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
	(b) (4)	
User entered 'bilateral pneumonia/sepsis'	Kelsey Kelley (b) (4)	09 Feb 2021 02:04:55
	(b) (4)	

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:48:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:37
DataPoint Verified.		07 Apr 2021 20:39:41
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
User entered '125'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 02:04:55

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:48:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:37
DataPoint Verified.		07 Apr 2021 20:39:41
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
User entered 'Other (OTHER)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 02:04:55

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:48:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:37
DataPoint Verified.		07 Apr 2021 20:39:41
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
User entered 'ml/hr'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 02:04:55

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:48:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:37
DataPoint Verified.		07 Apr 2021 20:39:41
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
User entered 'other (OTHER)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 02:04:55

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:48:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:37
DataPoint Verified.		07 Apr 2021 20:39:41
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
User entered 'Continuous'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 02:04:55



US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:48:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:37
DataPoint Verified.		07 Apr 2021 20:39:41
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 02:04:55

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:48:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:37
DataPoint Verified.		07 Apr 2021 20:39:41
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 02:04:55

**US3032115**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 14:48:59**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:37
DataPoint Verified.		07 Apr 2021 20:39:41
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
User entered '21 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 02:04:55

**US3032115**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 14:48:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:37
DataPoint Verified.		07 Apr 2021 20:39:41
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 02:04:55

**US3032115**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 14:48:59**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:37
DataPoint Verified.		07 Apr 2021 20:39:41
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 02:04:55

**US3032115**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 14:48:59**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:37
DataPoint Verified.		07 Apr 2021 20:39:41
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
User entered '24 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 02:04:55

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:48:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:37
DataPoint Verified.		07 Apr 2021 20:39:41
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 02:04:55

**US3032115**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 14:48:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:37
User entered empty.	System	09 Feb 2021 02:04:55



US3032115

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 14:48:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:37
User entered empty.	System	09 Feb 2021 02:04:55

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:48:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:37
User entered empty.	System	09 Feb 2021 02:04:55

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:48:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:33
DataPoint Verified.		07 Apr 2021 20:40:33
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: GLYCOPEPTIDE ANTIBACTERIALS, PRODUCT: VANCOMYCIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	05 Mar 2021 20:26:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	05 Mar 2021 20:26:07
Data point term sent to Coder Coding entries removed.	System Kelsey Kelley (b) (4)	05 Mar 2021 20:25:11 05 Mar 2021 20:24:35
User signature succeeded.	(b) (4) Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: GLYCOPEPTIDE ANTIBACTERIALS, PRODUCT: VANCOMYCIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	10 Feb 2021 08:42:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	10 Feb 2021 08:42:44
Data point term sent to Coder User entered 'vancomycin'	System Kelsey Kelley (b) (4)	09 Feb 2021 02:07:22 09 Feb 2021 02:06:48

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:48:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:33
DataPoint Verified.		07 Apr 2021 20:40:33
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 02:06:48

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:48:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:33
DataPoint Verified.		07 Apr 2021 20:40:33
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:21:18
Signature has been broken.	(b) (4) Kelsey Kelley (b) (4)	05 Mar 2021 20:24:35
User entered 'SEPSIS' reason for change: New Information	(b) (4) Kelsey Kelley (b) (4)	05 Mar 2021 20:24:35
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
User entered 'bilateral pneumonia/sepsis'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 02:06:48

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:48:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:33
DataPoint Verified.		07 Apr 2021 20:40:33
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
User entered '1250'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 02:06:48

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:48:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:33
DataPoint Verified.		07 Apr 2021 20:40:33
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
User entered 'mg (mg)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 02:06:48

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:48:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:33
DataPoint Verified.		07 Apr 2021 20:40:33
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 02:06:48



US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:48:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:33
DataPoint Verified.		07 Apr 2021 20:40:33
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
User entered 'other (OTHER)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 02:06:48

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:48:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:33
DataPoint Verified.		07 Apr 2021 20:40:33
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
User entered 'every 12 hours'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 02:06:48

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:48:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:33
DataPoint Verified.		07 Apr 2021 20:40:33
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 02:06:48

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:48:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:33
DataPoint Verified.		07 Apr 2021 20:40:33
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 02:06:48

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:48:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:33
DataPoint Verified.		07 Apr 2021 20:40:33
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
User entered '21 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 02:06:48

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:48:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:33
DataPoint Verified.		07 Apr 2021 20:40:33
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 02:06:48

**US3032115**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 14:48:59**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:33
DataPoint Verified.		07 Apr 2021 20:40:33
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 02:06:48

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:48:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:33
DataPoint Verified.		07 Apr 2021 20:40:33
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
User entered '24 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 02:06:48



US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:48:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:33
DataPoint Verified.		07 Apr 2021 20:40:33
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 02:06:48

US3032115

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 14:48:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:33
User entered empty.	System	09 Feb 2021 02:06:48

US3032115

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 14:48:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:33
User entered empty.	System	09 Feb 2021 02:06:48

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:48:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:33
User entered empty.	System	09 Feb 2021 02:06:48

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:48:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:28
DataPoint Verified.		07 Apr 2021 20:41:11
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: MONOBACTAMS, PRODUCT: AZTREONAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Mar 2021 04:56:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Mar 2021 04:56:59
Data point term sent to Coder	System	05 Mar 2021 20:25:12
Coding entries removed.	Kelsey Kelley (b) (4)	05 Mar 2021 20:24:46
User signature succeeded.	(b) (4)	
	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: MONOBACTAMS, PRODUCT: AZTREONAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Feb 2021 11:17:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Feb 2021 11:17:45
Data point term sent to Coder	System	09 Feb 2021 02:08:23
User entered 'aztreonam'	Kelsey Kelley (b) (4)	09 Feb 2021 02:08:04

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:48:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:28
DataPoint Verified.		07 Apr 2021 20:41:11
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 02:08:04

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:48:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:28
DataPoint Verified.		07 Apr 2021 20:41:11
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:21:18
Signature has been broken.	(b) (4) Kelsey Kelley (b) (4)	05 Mar 2021 20:24:46
User entered 'sEPSIS' reason for change: New Information	(b) (4) Kelsey Kelley (b) (4)	05 Mar 2021 20:24:46
User signature succeeded.	(b) (4) Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
User entered 'bilateral pneumonia/sepsis'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 02:08:04

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:48:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:28
DataPoint Verified.		07 Apr 2021 20:41:11
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
User entered '2000'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 02:08:04



US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:48:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:28
DataPoint Verified.		07 Apr 2021 20:41:11
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
User entered 'mg (mg)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 02:08:04

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:48:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:28
DataPoint Verified.		07 Apr 2021 20:41:11
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 02:08:04

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:48:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:28
DataPoint Verified.		07 Apr 2021 20:41:11
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
User entered 'other (OTHER)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 02:08:04

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:48:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:28
DataPoint Verified.		07 Apr 2021 20:41:11
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
User entered 'every 8 hours'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 02:08:04

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:48:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:28
DataPoint Verified.		07 Apr 2021 20:41:11
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 02:08:04

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:48:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:28
DataPoint Verified.		07 Apr 2021 20:41:11
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 02:08:04

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:48:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:28
DataPoint Verified.		07 Apr 2021 20:41:11
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
User entered '21 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 02:08:04

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:48:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:28
DataPoint Verified.		07 Apr 2021 20:41:11
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 02:08:04



**US3032115**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 14:48:59**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:28
DataPoint Verified.		07 Apr 2021 20:41:11
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 02:08:04

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:48:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:28
DataPoint Verified.		07 Apr 2021 20:41:11
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
User entered '24 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 02:08:04

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:48:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:28
DataPoint Verified.		07 Apr 2021 20:41:11
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 02:08:04

**US3032115**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 14:48:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:28
User entered empty.	System	09 Feb 2021 02:08:04

**US3032115**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 14:48:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:28
User entered empty.	System	09 Feb 2021 02:08:04

**US3032115**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 14:48:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:28
User entered empty.	System	09 Feb 2021 02:08:04

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:48:59

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:26
DataPoint Verified.	(b) (4)	07 Apr 2021 20:42:29
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)	07 Mar 2021 22:37:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Mar 2021 22:37:55
Data point term sent to Coder	System	05 Mar 2021 20:25:12
Coding entries removed.	Kelsey Kelley (b) (4)	05 Mar 2021 20:24:54
User signature succeeded.	(b) (4)	
	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
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)	09 Feb 2021 09:46:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Feb 2021 09:46:44
Data point term sent to Coder	System	09 Feb 2021 02:09:23
User entered 'lovenox (enoxaparin)'	Kelsey Kelley (b) (4)	09 Feb 2021 02:08:55

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:48:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:26
DataPoint Verified.		07 Apr 2021 20:42:29
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 02:08:55



US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:48:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:26
DataPoint Verified.		07 Apr 2021 20:42:29
User signature succeeded.	Keith Vrbicky (b) (4)	10 Mar 2021 15:21:18
Signature has been broken.	(b) (4) Kelsey Kelley (b) (4)	05 Mar 2021 20:24:54
User entered 'SEPSIS' reason for change: New Information	(b) (4) Kelsey Kelley (b) (4)	05 Mar 2021 20:24:54
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
User entered 'bilateral pneumonia/sepsis'	(b) (4) Kelsey Kelley (b) (4)	09 Feb 2021 02:08:55

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:48:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:26
DataPoint Verified.		07 Apr 2021 20:42:29
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
User entered '40'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 02:08:55

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:48:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:26
DataPoint Verified.		07 Apr 2021 20:42:29
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
User entered 'mg (mg)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 02:08:55

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:48:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:26
DataPoint Verified.		07 Apr 2021 20:42:29
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 02:08:55

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:48:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:26
DataPoint Verified.		07 Apr 2021 20:42:29
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
User entered 'once daily (QD)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 02:08:55

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:48:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:26
DataPoint Verified.		07 Apr 2021 20:42:29
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 02:08:55

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:48:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:26
DataPoint Verified.		07 Apr 2021 20:42:29
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 02:08:55

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:48:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:26
DataPoint Verified.		07 Apr 2021 20:42:29
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 02:08:55



US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:48:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:26
DataPoint Verified.		07 Apr 2021 20:42:29
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
User entered '21 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 02:08:55

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:48:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:26
DataPoint Verified.		07 Apr 2021 20:42:29
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 02:08:55

**US3032115**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 14:48:59**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:26
DataPoint Verified.		07 Apr 2021 20:42:29
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 02:08:55

**US3032115**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 14:48:59**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:26
DataPoint Verified.		07 Apr 2021 20:42:29
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
User entered '24 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 02:08:55

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:48:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:26
DataPoint Verified.		07 Apr 2021 20:42:29
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Feb 2021 02:08:55

**US3032115**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 14:48:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:26
User entered '1'	System	09 Feb 2021 02:08:55

US3032115

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 14:48:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:26
User entered '1'	System	09 Feb 2021 02:08:55

**US3032115**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 14:48:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:20:26
User entered '804 (804)'	System	09 Feb 2021 02:08:55



US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:48:59

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:42:47
User signature succeeded.	(b) (4)	25 Mar 2021 14:17:35
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: EVOLOCUMAB, PRODUCTSYNONYM: REPATHA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	(b) (4) 17 Mar 2021 11:59:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	(b) (4) 17 Mar 2021 11:59:43
Data point term sent to Coder Coding entries removed.	System Kelsey Kelley (b) (4)	16 Mar 2021 22:06:17 16 Mar 2021 22:05:31
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: EVOLOCUMAB, PRODUCTSYNONYM: REPATHA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	(b) (4) 16 Mar 2021 20:41:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	(b) (4) 16 Mar 2021 20:41:54
Data point term sent to Coder User entered 'repatha (evolocumab)'	System Kelsey Kelley (b) (4)	16 Mar 2021 20:41:33 16 Mar 2021 20:40:33

**US3032115**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 14:48:59**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:42:47
User signature succeeded.	Keith Vrbicky (b) (4)	25 Mar 2021 14:17:35
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	16 Mar 2021 20:40:33
	(b) (4)	

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:48:59

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:42:47
User signature succeeded.	Keith Vrbicky (b) (4)	25 Mar 2021 14:17:35
User entered 'Homozygous familial hypercholesterolemia' reason for change: Data Entry Error	(b) (4)	16 Mar 2021 22:05:31
User entered 'hyperlipidemia'	Kelsey Kelley (b) (4)	16 Mar 2021 20:40:33
	(b) (4)	

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:48:59

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:42:47
User signature succeeded.	Keith Vrbicky (b) (4)	25 Mar 2021 14:17:35
User entered '420'	(b) (4) Kelsey Kelley (b) (4)	16 Mar 2021 20:40:33
	(b) (4)	

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:48:59

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:42:47
User signature succeeded.	Keith Vrbicky (b) (4)	25 Mar 2021 14:17:35
User entered 'mg (mg)'	(b) (4) Kelsey Kelley (b) (4)	16 Mar 2021 20:40:33
	(b) (4)	

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:48:59

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:42:47
User signature succeeded.	Keith Vrbicky (b) (4)	25 Mar 2021 14:17:35
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	16 Mar 2021 20:40:33
	(b) (4)	

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:48:59

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:42:47
User signature succeeded.	Keith Vrbicky (b) (4)	25 Mar 2021 14:17:35
User entered 'every month (QM)'	(b) (4) Kelsey Kelley (b) (4)	16 Mar 2021 20:40:33
	(b) (4)	

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:48:59

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:42:47
User signature succeeded.	Keith Vrbicky (b) (4)	25 Mar 2021 14:17:35
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	16 Mar 2021 20:40:33
	(b) (4)	



US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:48:59

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:42:47
User signature succeeded.	Keith Vrbicky (b) (4)	25 Mar 2021 14:17:35
User entered 'Subcutaneous (SUBCUTANEOUS)'	Kelsey Kelley (b) (4)	16 Mar 2021 20:40:33

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:48:59

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:42:47
User signature succeeded.	Keith Vrbicky (b) (4)	25 Mar 2021 14:17:35
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	16 Mar 2021 20:40:33
	(b) (4)	

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:48:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:42:47
User signature succeeded.	Keith Vrbicky (b) (4)	25 Mar 2021 14:17:35
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	(b) (4)	16 Mar 2021 22:05:31
User entered 'un Oct 2020' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	16 Mar 2021 22:05:31
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	16 Mar 2021 20:40:33
User entered empty.	Kelsey Kelley (b) (4)	16 Mar 2021 20:40:33

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:48:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:42:47
User signature succeeded.	Keith Vrbicky (b) (4)	25 Mar 2021 14:17:35
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	16 Mar 2021 20:40:33
	(b) (4)	

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:48:59

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:42:47
User signature succeeded.	Keith Vrbicky (b) (4)	25 Mar 2021 14:17:35
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Kelsey Kelley (b) (4)	16 Mar 2021 22:05:38
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	System	16 Mar 2021 22:05:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Mar 2021 22:05:31
User entered 'No (N)' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	16 Mar 2021 22:05:31
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Mar 2021 20:40:33
User entered empty.	Kelsey Kelley (b) (4)	16 Mar 2021 20:40:33
	(b) (4)	

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:48:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:42:47
User signature succeeded.	Keith Vrbicky (b) (4)	25 Mar 2021 14:17:35
User closed query 'Ongoing is No, however End date System is missing. Please provide.' (Site from System).	(b) (4)	16 Mar 2021 22:05:38
User opened query 'Ongoing is No, however End dateSystem is missing. Please provide.' (Site from System).		16 Mar 2021 22:05:31
User entered empty.	Kelsey Kelley (b) (4)	16 Mar 2021 20:40:33
	(b) (4)	

US3032115

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:48:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:42:47
User signature succeeded.	Keith Vrbicky (b) (4)	25 Mar 2021 14:17:35
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Mar 2021 22:05:31
User entered 'No (N)' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	16 Mar 2021 22:05:31
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	16 Mar 2021 20:40:33
	Kelsey Kelley (b) (4)	16 Mar 2021 20:40:33
	(b) (4)	

**US3032115**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 14:48:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Mar 2021 20:40:33



**US3032115**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 14:48:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Mar 2021 20:40:33

**US3032115**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 14:48:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '802 (802)'	System	16 Mar 2021 20:40:33

US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 14:48:59

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:09:00
DataPoint Verified.		07 Apr 2021 20:42:56
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
DataPoint Un-verified.	(b) (4)	
	Kelsey Kelley (b) (4)	16 Mar 2021 20:27:58
Signature has been broken.	(b) (4)	
	Kelsey Kelley (b) (4)	16 Mar 2021 20:27:58
User entered 'Yes (Y)' reason for change: New Information	(b) (4)	
	Kelsey Kelley (b) (4)	16 Mar 2021 20:27:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 20:10:35
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:59:27
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	06 Aug 2020 21:08:56
	(b) (4)	

US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:48:59

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:43:59
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered '22 Dec 2020'	(b) (4) Kelsey Kelley (b) (4)	16 Mar 2021 20:28:50
	(b) (4)	

US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:48:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:43:59
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'CT of soft tissue of neck'	Kelsey Kelley (b) (4)	16 Mar 2021 20:28:50

US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:48:59

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:43:59
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'Adverse Event (AE)'	Kelsey Kelley (b) (4)	16 Mar 2021 20:28:50

US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:48:59

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:43:59
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	16 Mar 2021 20:28:50
	(b) (4)	

US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:48:59

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:01
DataPoint Verified.		07 Apr 2021 20:44:13
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered '22 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:29:24



US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:48:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:01
DataPoint Verified.		07 Apr 2021 20:44:13
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'ct angiogram of chest'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:29:24

US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:48:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:01
DataPoint Verified.		07 Apr 2021 20:44:13
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'Adverse Event (AE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:29:24

US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:48:59

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:01
DataPoint Verified.		07 Apr 2021 20:44:13
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:29:24

US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 14:48:59

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:05
DataPoint Verified.		07 Apr 2021 20:44:22
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered '22 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:29:46

US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 14:48:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:05
DataPoint Verified.		07 Apr 2021 20:44:22
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'ct abdomen/pelvis'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:29:46

US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 14:48:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:05
DataPoint Verified.		07 Apr 2021 20:44:22
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'Adverse Event (AE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:29:46

US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 14:48:59

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:05
DataPoint Verified.		07 Apr 2021 20:44:22
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:29:46

US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 14:48:59

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:08
DataPoint Verified.		07 Apr 2021 20:44:28
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered '22 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:30:02



US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 14:48:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:08
DataPoint Verified.		07 Apr 2021 20:44:28
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'influenza testing'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:30:02

US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 14:48:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:08
DataPoint Verified.		07 Apr 2021 20:44:28
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'Adverse Event (AE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:30:02

US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 14:48:59

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:08
DataPoint Verified.		07 Apr 2021 20:44:28
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:30:02

US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 14:48:59

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:13
DataPoint Verified.		07 Apr 2021 20:45:24
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered '22 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:30:17

US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 14:48:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:13
DataPoint Verified.		07 Apr 2021 20:45:24
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'covid-19 PCr'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:30:17

US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 14:48:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:13
DataPoint Verified.		07 Apr 2021 20:45:24
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'Adverse Event (AE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:30:17

US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 14:48:59

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:13
DataPoint Verified.		07 Apr 2021 20:45:24
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:30:17

US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 14:48:59

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:16
DataPoint Verified.		07 Apr 2021 20:45:24
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered '22 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:30:35



US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 14:48:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:16
DataPoint Verified.		07 Apr 2021 20:45:24
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'blood cultures'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:30:35

US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 14:48:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:16
DataPoint Verified.		07 Apr 2021 20:45:24
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'Adverse Event (AE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:30:35

US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 14:48:59

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:16
DataPoint Verified.		07 Apr 2021 20:45:24
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:30:35

US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 14:48:59

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:18
DataPoint Verified.		07 Apr 2021 20:45:24
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered '22 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:30:55

US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 14:48:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:18
DataPoint Verified.		07 Apr 2021 20:45:24
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'lactic acid'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:30:55

US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 14:48:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:18
DataPoint Verified.		07 Apr 2021 20:45:24
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'Adverse Event (AE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:30:55

US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 14:48:59

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:18
DataPoint Verified.		07 Apr 2021 20:45:24
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:30:55

US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 14:48:59

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:24
DataPoint Verified.		07 Apr 2021 20:45:24
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered '22 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:31:19



US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 14:48:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:24
DataPoint Verified.		07 Apr 2021 20:45:24
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'covid-19 antibody'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:31:19

US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 14:48:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:24
DataPoint Verified.		07 Apr 2021 20:45:24
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'Adverse Event (AE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:31:19

US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 14:48:59

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:24
DataPoint Verified.		07 Apr 2021 20:45:24
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:31:19

US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 14:48:59

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:32
DataPoint Verified.		07 Apr 2021 20:45:24
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered '22 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:31:41

US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 14:48:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:32
DataPoint Verified.		07 Apr 2021 20:45:24
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'procalcitonin'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:31:41

US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 14:48:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:32
DataPoint Verified.		07 Apr 2021 20:45:24
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'Adverse Event (AE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:31:41

US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 14:48:59

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:32
DataPoint Verified.		07 Apr 2021 20:45:24
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:31:41

US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 14:48:59

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:33
DataPoint Verified.		07 Apr 2021 20:45:24
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered '22 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:32:42



US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 14:48:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:33
DataPoint Verified.		07 Apr 2021 20:45:24
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'd-dimer'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:32:42

US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 14:48:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:33
DataPoint Verified.		07 Apr 2021 20:45:24
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'Adverse Event (AE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:32:42

US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 14:48:59

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:33
DataPoint Verified.		07 Apr 2021 20:45:24
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:32:42

US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 14:48:59

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:38
DataPoint Verified.		07 Apr 2021 20:45:24
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered '22 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:33:36

US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 14:48:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:38
DataPoint Verified.		07 Apr 2021 20:45:24
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'troponin'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:33:36

US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 14:48:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:38
DataPoint Verified.		07 Apr 2021 20:45:24
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'Adverse Event (AE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:33:36

US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 14:48:59

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:38
DataPoint Verified.		07 Apr 2021 20:45:24
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:33:36

US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 09 Jun 2021 14:48:59

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:42
DataPoint Verified.		07 Apr 2021 20:45:24
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered '22 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:33:48



US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 09 Jun 2021 14:48:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:42
DataPoint Verified.		07 Apr 2021 20:45:24
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'hiv testing'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:33:48

US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 09 Jun 2021 14:48:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:42
DataPoint Verified.		07 Apr 2021 20:45:24
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'Adverse Event (AE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:33:48

US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 09 Jun 2021 14:48:59

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:42
DataPoint Verified.		07 Apr 2021 20:45:24
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:33:48

US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (13)

Generated On: 09 Jun 2021 14:48:59

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:46
DataPoint Verified.		07 Apr 2021 20:45:24
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered '22 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:34:09

US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (13)

Generated On: 09 Jun 2021 14:48:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:46
DataPoint Verified.		07 Apr 2021 20:45:24
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'respiratory viral panel'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:34:09

US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (13)

Generated On: 09 Jun 2021 14:48:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:46
DataPoint Verified.		07 Apr 2021 20:45:24
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'Adverse Event (AE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:34:09

US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (13)

Generated On: 09 Jun 2021 14:48:59

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:46
DataPoint Verified.		07 Apr 2021 20:45:24
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:34:09

US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (14)

Generated On: 09 Jun 2021 14:48:59

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:57
DataPoint Verified.		07 Apr 2021 20:45:24
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered '22 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:35:24



US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (14)

Generated On: 09 Jun 2021 14:48:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:57
DataPoint Verified.		07 Apr 2021 20:45:24
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'Fungitell testing'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:35:24

US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (14)

Generated On: 09 Jun 2021 14:48:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:57
DataPoint Verified.		07 Apr 2021 20:45:24
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'Adverse Event (AE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:35:24

US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (14)

Generated On: 09 Jun 2021 14:48:59

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:57
DataPoint Verified.		07 Apr 2021 20:45:24
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:35:24

US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (15)

Generated On: 09 Jun 2021 14:48:59

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:59
DataPoint Verified.		07 Apr 2021 20:45:24
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered '22 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:36:17

US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (15)

Generated On: 09 Jun 2021 14:48:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:59
DataPoint Verified.		07 Apr 2021 20:45:24
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'aspergillus galactomannan testing'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:36:17

US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (15)

Generated On: 09 Jun 2021 14:48:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:59
DataPoint Verified.		07 Apr 2021 20:45:24
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'Adverse Event (AE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:36:17

US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (15)

Generated On: 09 Jun 2021 14:48:59

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:55:59
DataPoint Verified.		07 Apr 2021 20:45:24
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:36:17

US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (16)

Generated On: 09 Jun 2021 14:48:59

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:56:01
DataPoint Verified.		07 Apr 2021 20:45:24
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered '22 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:36:35



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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (16)

Generated On: 09 Jun 2021 14:48:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:56:01
DataPoint Verified.		07 Apr 2021 20:45:24
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'complete blood count'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:36:35

US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (16)

Generated On: 09 Jun 2021 14:48:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:56:01
DataPoint Verified.		07 Apr 2021 20:45:24
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'Adverse Event (AE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:36:35

US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (16)

Generated On: 09 Jun 2021 14:48:59

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:56:01
DataPoint Verified.		07 Apr 2021 20:45:24
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:36:35

US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (17)

Generated On: 09 Jun 2021 14:48:59

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:56:05
DataPoint Verified.		07 Apr 2021 20:45:24
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered '22 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:36:55

US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (17)

Generated On: 09 Jun 2021 14:48:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:56:05
DataPoint Verified.		07 Apr 2021 20:45:24
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'complete metabolic panel'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:36:55

US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (17)

Generated On: 09 Jun 2021 14:48:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:56:05
DataPoint Verified.		07 Apr 2021 20:45:24
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'Adverse Event (AE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:36:55

US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (17)

Generated On: 09 Jun 2021 14:48:59

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:56:05
DataPoint Verified.		07 Apr 2021 20:45:24
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:36:55

US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (18)

Generated On: 09 Jun 2021 14:48:59

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:56:08
DataPoint Verified.		07 Apr 2021 20:45:24
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered '09 Dec 2020' reason for change: Data Entry Error	(b) (4)	
	Kelsey Kelley (b) (4)	16 Mar 2021 20:37:21
User entered '22 Dec 2020'	(b) (4)	
	Kelsey Kelley (b) (4)	16 Mar 2021 20:37:13
	(b) (4)	



US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (18)

Generated On: 09 Jun 2021 14:48:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:56:08
DataPoint Verified.		07 Apr 2021 20:45:24
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'study-related covid-19 test'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:37:13

US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (18)

Generated On: 09 Jun 2021 14:48:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:56:08
DataPoint Verified.		07 Apr 2021 20:45:24
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'Adverse Event (AE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:37:13

US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (18)

Generated On: 09 Jun 2021 14:48:59

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:56:08
DataPoint Verified.		07 Apr 2021 20:45:24
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:37:13

US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (19)

Generated On: 09 Jun 2021 14:48:59

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:56:12
DataPoint Verified.		07 Apr 2021 20:45:24
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered '10 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:37:43

US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (19)

Generated On: 09 Jun 2021 14:48:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:56:12
DataPoint Verified.		07 Apr 2021 20:45:24
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'rapid covid-19 Test'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:37:43

US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (19)

Generated On: 09 Jun 2021 14:48:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:56:12
DataPoint Verified.		07 Apr 2021 20:45:24
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'Adverse Event (AE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:37:43

US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (19)

Generated On: 09 Jun 2021 14:48:59

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:56:12
DataPoint Verified.		07 Apr 2021 20:45:24
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:37:43

US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (20)

Generated On: 09 Jun 2021 14:48:59

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:56:13
DataPoint Verified.		07 Apr 2021 20:45:24
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered '18 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:37:56



US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (20)

Generated On: 09 Jun 2021 14:48:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:56:13
DataPoint Verified.		07 Apr 2021 20:45:24
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'covid-19 pcr test'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:37:56

US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (20)

Generated On: 09 Jun 2021 14:48:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:56:13
DataPoint Verified.		07 Apr 2021 20:45:24
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'Adverse Event (AE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:37:56

US3032115

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (20)

Generated On: 09 Jun 2021 14:48:59

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:56:13
DataPoint Verified.		07 Apr 2021 20:45:24
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	16 Mar 2021 20:37:56

**US3032115**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:48:59**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'USA-US032-2021-MRNA-1273-P301000001'	System	04 Jan 2021 18:24:27

**US3032115**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:48:59**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'Yes (Y)'	System	04 Jan 2021 18:24:27

**US3032115**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:48:59**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'No (N)'	System	04 Jan 2021 18:24:27

**US3032115**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:48:59**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'No (N)'	System	04 Jan 2021 18:24:27

**US3032115**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:48:59**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'Yes (Y)'	System	04 Jan 2021 18:24:27



**US3032115**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:48:59**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'No (N)'	System	04 Jan 2021 18:24:27

**US3032115**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:48:59**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'No (N)'	System	04 Jan 2021 18:24:27

**US3032115**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:48:59**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'No (N)'	System	04 Jan 2021 18:24:27

US3032115

Folder: SAE USA-US032-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'Keith'	System	04 Jan 2021 18:24:27

US3032115

Folder: SAE USA-US032-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'Vrbicky'	System	04 Jan 2021 18:24:27

US3032115

Folder: SAE USA-US032-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:59

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'US'	System	04 Jan 2021 18:28:54

US3032115

Folder: SAE USA-US032-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	17 Mar 2021 16:58:11
Signature has been broken.	System	26 Feb 2021 15:01:35
User entered '5'	System	26 Feb 2021 15:01:35
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
	(b) (4)	
User entered '4'	System	11 Feb 2021 13:46:34
Signature has been broken.	System	09 Feb 2021 13:40:05
User entered '3'	System	09 Feb 2021 13:40:05
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:39:23
	(b) (4)	
Signature has been broken.	System	02 Feb 2021 15:33:24
User entered '2'	System	02 Feb 2021 15:33:24
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
	(b) (4)	
User entered '1'	System	04 Jan 2021 18:28:54

**US3032115**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:48:59**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'USA-US032-2021-MRNA-1273-P301000001'	System	04 Jan 2021 18:24:27



**US3032115**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:48:59**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'Yes (Y)'	System	04 Jan 2021 18:24:27

**US3032115**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:48:59**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'No (N)'	System	04 Jan 2021 18:24:27

**US3032115**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:48:59**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'No (N)'	System	04 Jan 2021 18:24:27

**US3032115**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:48:59**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'Yes (Y)'	System	04 Jan 2021 18:24:27

US3032115

Folder: SAE USA-US032-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'No (N)'	System	04 Jan 2021 18:24:27

**US3032115**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:48:59**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'No (N)'	System	04 Jan 2021 18:24:27

US3032115

Folder: SAE USA-US032-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:59

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'No (N)'	System	04 Jan 2021 18:24:27

US3032115

Folder: SAE USA-US032-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'Keith'	System	04 Jan 2021 18:24:27



US3032115

Folder: SAE USA-US032-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'Vrbicky'	System	04 Jan 2021 18:24:27

US3032115

Folder: SAE USA-US032-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:59

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'US'	System	04 Jan 2021 18:28:54

US3032115

Folder: SAE USA-US032-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	17 Mar 2021 16:58:11
Signature has been broken.	System	26 Feb 2021 15:01:35
User entered '5'	System	26 Feb 2021 15:01:35
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
	(b) (4)	
User entered '4'	System	11 Feb 2021 13:46:34
Signature has been broken.	System	09 Feb 2021 13:40:05
User entered '3'	System	09 Feb 2021 13:40:05
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:39:23
	(b) (4)	
Signature has been broken.	System	02 Feb 2021 15:33:24
User entered '2'	System	02 Feb 2021 15:33:24
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
	(b) (4)	
User entered '1'	System	04 Jan 2021 18:28:54

**US3032115**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000001**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 14:48:59**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
User entered '04/Jan/2021 13:28'	(b) (4) System	04 Jan 2021 18:28:54

US3032115

Folder: SAE USA-US032-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:48:59

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'I'		04 Jan 2021 18:28:54

**US3032115**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:48:59**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'USA-US032-2021-MRNA-1273-P301000001'	System	04 Jan 2021 18:24:27

**US3032115**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:48:59**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'Yes (Y)'	System	04 Jan 2021 18:24:27

**US3032115**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:48:59**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'No (N)'	System	04 Jan 2021 18:24:27



US3032115

Folder: SAE USA-US032-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:59

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'No (N)'	System	04 Jan 2021 18:24:27

**US3032115**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:48:59**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'Yes (Y)'	System	04 Jan 2021 18:24:27

**US3032115**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:48:59**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	4 Apr 2021 20:07:47
Reviewed for Safety.		1 Feb 2021 13:46:07
Un-reviewed for Safety.		1 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'No (N)'	System	04 Jan 2021 18:24:27

**US3032115**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:48:59**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'No (N)'	System	04 Jan 2021 18:24:27

**US3032115**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:48:59**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'No (N)'	System	04 Jan 2021 18:24:27

US3032115

Folder: SAE USA-US032-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'Keith'	System	04 Jan 2021 18:24:27

US3032115

Folder: SAE USA-US032-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'Vrbicky'	System	04 Jan 2021 18:24:27

US3032115

Folder: SAE USA-US032-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:59

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'US'	System	04 Jan 2021 18:28:54



US3032115

Folder: SAE USA-US032-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	17 Mar 2021 16:58:11
Signature has been broken.	System	26 Feb 2021 15:01:35
User entered '5'	System	26 Feb 2021 15:01:35
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
	(b) (4)	
User entered '4'	System	11 Feb 2021 13:46:34
Signature has been broken.	System	09 Feb 2021 13:40:05
User entered '3'	System	09 Feb 2021 13:40:05
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:39:23
	(b) (4)	
Signature has been broken.	System	02 Feb 2021 15:33:24
User entered '2'	System	02 Feb 2021 15:33:24
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
	(b) (4)	
User entered '1'	System	04 Jan 2021 18:28:54

**US3032115**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000001**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 14:48:59**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:39:23
User entered '02/Feb/2021 10:33'	(b) (4) System	02 Feb 2021 15:33:24

US3032115

Folder: SAE USA-US032-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:48:59

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
Reviewed for Safety.		09 Feb 2021 13:39:54
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:39:23
User entered 'I'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 15:33:24

**US3032115**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:48:59**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'USA-US032-2021-MRNA-1273-P301000001'	System	04 Jan 2021 18:24:27

**US3032115**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:48:59**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'Yes (Y)'	System	04 Jan 2021 18:24:27

**US3032115**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:48:59**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'No (N)'	System	04 Jan 2021 18:24:27

US3032115

Folder: SAE USA-US032-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:59

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'No (N)'	System	04 Jan 2021 18:24:27

**US3032115**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:48:59**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'Yes (Y)'	System	04 Jan 2021 18:24:27



US3032115

Folder: SAE USA-US032-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'No (N)'	System	04 Jan 2021 18:24:27

**US3032115**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:48:59**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'No (N)'	System	04 Jan 2021 18:24:27

US3032115

Folder: SAE USA-US032-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:59

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	4 Apr 2021 20:07:47
Reviewed for Safety.		1 Feb 2021 13:46:07
Un-reviewed for Safety.		1 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'No (N)'	System	04 Jan 2021 18:24:27

US3032115

Folder: SAE USA-US032-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'Keith'	System	04 Jan 2021 18:24:27

US3032115

Folder: SAE USA-US032-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'Vrbicky'	System	04 Jan 2021 18:24:27

US3032115

Folder: SAE USA-US032-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:59

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'US'	System	04 Jan 2021 18:28:54

US3032115

Folder: SAE USA-US032-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	17 Mar 2021 16:58:11
Signature has been broken.	System	26 Feb 2021 15:01:35
User entered '5'	System	26 Feb 2021 15:01:35
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
	(b) (4)	
User entered '4'	System	11 Feb 2021 13:46:34
Signature has been broken.	System	09 Feb 2021 13:40:05
User entered '3'	System	09 Feb 2021 13:40:05
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:39:23
	(b) (4)	
Signature has been broken.	System	02 Feb 2021 15:33:24
User entered '2'	System	02 Feb 2021 15:33:24
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
	(b) (4)	
User entered '1'	System	04 Jan 2021 18:28:54

**US3032115**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000001**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 14:48:59**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
User entered '09/Feb/2021 08:40'	(b) (4) System	09 Feb 2021 13:40:05



US3032115

Folder: SAE USA-US032-2021-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 14:48:59

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
Reviewed for Safety.		11 Feb 2021 13:45:40
User entered 'I'		09 Feb 2021 13:40:05

**US3032115**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:48:59**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'USA-US032-2021-MRNA-1273-P301000001'	System	04 Jan 2021 18:24:27

**US3032115**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:48:59**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'Yes (Y)'	System	04 Jan 2021 18:24:27

**US3032115**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:48:59**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'No (N)'	System	04 Jan 2021 18:24:27

**US3032115**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:48:59**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'No (N)'	System	04 Jan 2021 18:24:27

**US3032115**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:48:59**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'Yes (Y)'	System	04 Jan 2021 18:24:27

US3032115

Folder: SAE USA-US032-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'No (N)'	System	04 Jan 2021 18:24:27

US3032115

Folder: SAE USA-US032-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'No (N)'	System	04 Jan 2021 18:24:27



**US3032115**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:48:59**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'No (N)'	System	04 Jan 2021 18:24:27

US3032115

Folder: SAE USA-US032-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'Keith'	System	04 Jan 2021 18:24:27

US3032115

Folder: SAE USA-US032-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'Vrbicky'	System	04 Jan 2021 18:24:27

US3032115

Folder: SAE USA-US032-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:59

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'US'	System	04 Jan 2021 18:28:54

US3032115

Folder: SAE USA-US032-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	17 Mar 2021 16:58:11
Signature has been broken.	System	26 Feb 2021 15:01:35
User entered '5'	System	26 Feb 2021 15:01:35
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
	(b) (4)	
User entered '4'	System	11 Feb 2021 13:46:34
Signature has been broken.	System	09 Feb 2021 13:40:05
User entered '3'	System	09 Feb 2021 13:40:05
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:39:23
	(b) (4)	
Signature has been broken.	System	02 Feb 2021 15:33:24
User entered '2'	System	02 Feb 2021 15:33:24
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
	(b) (4)	
User entered '1'	System	04 Jan 2021 18:28:54

**US3032115**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000001**

**Form: Safety Report Form (4)**

**Generated On: 09 Jun 2021 14:48:59**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
User entered '11/Feb/2021 08:46'	(b) (4) System	11 Feb 2021 13:46:34

US3032115

Folder: SAE USA-US032-2021-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 14:48:59

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 15:03:48
User entered 'I'		11 Feb 2021 13:46:34

**US3032115**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:48:59**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'USA-US032-2021-MRNA-1273-P301000001'	System	04 Jan 2021 18:24:27



**US3032115**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:48:59**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'Yes (Y)'	System	04 Jan 2021 18:24:27

**US3032115**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:48:59**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'No (N)'	System	04 Jan 2021 18:24:27

US3032115

Folder: SAE USA-US032-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:59

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'No (N)'	System	04 Jan 2021 18:24:27

**US3032115**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:48:59**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'Yes (Y)'	System	04 Jan 2021 18:24:27

US3032115

Folder: SAE USA-US032-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'No (N)'	System	04 Jan 2021 18:24:27

US3032115

Folder: SAE USA-US032-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	4 Apr 2021 20:07:47
Reviewed for Safety.		1 Feb 2021 13:46:07
Un-reviewed for Safety.		1 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'No (N)'	System	04 Jan 2021 18:24:27

US3032115

Folder: SAE USA-US032-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:59

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	4 Apr 2021 20:07:47
Reviewed for Safety.		1 Feb 2021 13:46:07
Un-reviewed for Safety.		1 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'No (N)'	System	04 Jan 2021 18:24:27

US3032115

Folder: SAE USA-US032-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'Keith'	System	04 Jan 2021 18:24:27



US3032115

Folder: SAE USA-US032-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'Vrbicky'	System	04 Jan 2021 18:24:27

US3032115

Folder: SAE USA-US032-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:59

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'US'	System	04 Jan 2021 18:28:54

US3032115

Folder: SAE USA-US032-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	17 Mar 2021 16:58:11
Signature has been broken.	System	26 Feb 2021 15:01:35
User entered '5'	System	26 Feb 2021 15:01:35
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
	(b) (4)	
User entered '4'	System	11 Feb 2021 13:46:34
Signature has been broken.	System	09 Feb 2021 13:40:05
User entered '3'	System	09 Feb 2021 13:40:05
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:39:23
	(b) (4)	
Signature has been broken.	System	02 Feb 2021 15:33:24
User entered '2'	System	02 Feb 2021 15:33:24
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
	(b) (4)	
User entered '1'	System	04 Jan 2021 18:28:54

**US3032115**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000001**

**Form: Safety Report Form (5)**

**Generated On: 09 Jun 2021 14:48:59**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:02:05
User entered '26/Feb/2021 15:01'	(b) (4) System	26 Feb 2021 15:01:35

US3032115

Folder: SAE USA-US032-2021-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 14:48:59

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		17 Mar 2021 16:57:44
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:02:05
User entered 'I'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:01:35

**US3032115**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:48:59**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'USA-US032-2021-MRNA-1273-P301000001'	System	04 Jan 2021 18:24:27

**US3032115**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:48:59**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'Yes (Y)'	System	04 Jan 2021 18:24:27

**US3032115**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:48:59**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'No (N)'	System	04 Jan 2021 18:24:27



**US3032115**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:48:59**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'No (N)'	System	04 Jan 2021 18:24:27

**US3032115**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:48:59**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'Yes (Y)'	System	04 Jan 2021 18:24:27

US3032115

Folder: SAE USA-US032-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'No (N)'	System	04 Jan 2021 18:24:27

**US3032115**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:48:59**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'No (N)'	System	04 Jan 2021 18:24:27

US3032115

Folder: SAE USA-US032-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:59

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'No (N)'	System	04 Jan 2021 18:24:27

US3032115

Folder: SAE USA-US032-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'Keith'	System	04 Jan 2021 18:24:27

US3032115

Folder: SAE USA-US032-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'Vrbicky'	System	04 Jan 2021 18:24:27

**US3032115**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:48:59**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
Reviewed for Safety.		11 Feb 2021 13:46:07
Un-reviewed for Safety.		11 Feb 2021 13:46:02
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:28:57
User entered 'US'	System	04 Jan 2021 18:28:54



US3032115

Folder: SAE USA-US032-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:48:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	17 Mar 2021 16:58:11
Signature has been broken.	System	26 Feb 2021 15:01:35
User entered '5'	System	26 Feb 2021 15:01:35
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:54:32
	(b) (4)	
User entered '4'	System	11 Feb 2021 13:46:34
Signature has been broken.	System	09 Feb 2021 13:40:05
User entered '3'	System	09 Feb 2021 13:40:05
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:39:23
	(b) (4)	
Signature has been broken.	System	02 Feb 2021 15:33:24
User entered '2'	System	02 Feb 2021 15:33:24
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:16:01
	(b) (4)	
User entered '1'	System	04 Jan 2021 18:28:54

**US3032115**

**Folder: SAE USA-US032-2021-MRNA-1273-P301000001**

**Form: Safety Report Form (6)**

**Generated On: 09 Jun 2021 14:48:59**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered '17/Mar/2021 12:58'	(b) (4) System	17 Mar 2021 16:58:11

US3032115

Folder: SAE USA-US032-2021-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 14:48:59

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 20:07:47
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:11:10
User entered 'I'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 16:58:11