

US3312130 (Prod: Johnson County Clin-Trials)

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:58:40

All time stamps listed in this document are displayed in GMT

US3312130

Form: Participant Creation

Data signed: (b) (4) 05 Apr 2021 18:16:43

Generated On: 09 Jun 2021 16:58:40

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Participant ID

US3312130

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

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US3312130

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 21:56:40

Generated On: 09 Jun 2021 16:58:40

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 21:56:40

Generated On: 09 Jun 2021 16:58:40

Date of Birth (MMM yyyy)	(b) (6) 1970
Age	50
Age Units	YEARS
Age (Derived)	50
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False



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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 21:56:40

Generated On: 09 Jun 2021 16:58:40

Date of Informed Consent ( <i>dd MMM yyyy</i> )	18 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 21:56:40

Generated On: 09 Jun 2021 16:58:40

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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) 15 Feb 2021 21:56:40

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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) 08 Apr 2021 15:18:30

Generated On: 09 Jun 2021 16:58:40

Condition	DIABETES MELLITUS TYPE II
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 (2)

Data signed: (b) (4) 08 Apr 2021 15:18:30

Generated On: 09 Jun 2021 16:58:40

Condition	HYPERTENSION
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 (3)

Data signed: (b) (4) 08 Apr 2021 15:18:30

Generated On: 09 Jun 2021 16:58:40

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

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 08 Apr 2021 15:18:30

Generated On: 09 Jun 2021 16:58:40

Condition	ANGIOPLASTY
Start date (dd MMM yyyy)	13 NOV 2017
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)	13 NOV 2017
Stop date completely unknown	False
Start Month and Year (derived)	NOV 2017
Start Year (derived)	2017
Stop Month and Year (derived)	NOV 2017
Stop Year (derived)	2017

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 08 Apr 2021 15:18:30

Generated On: 09 Jun 2021 16:58:40

Condition	RIGHT BICEP TENDON TEAR
Start date (dd MMM yyyy)	UN DEC 2018
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 DEC 2018
Stop date completely unknown	False
Start Month and Year (derived)	DEC 2018
Start Year (derived)	2018
Stop Month and Year (derived)	DEC 2018
Stop Year (derived)	2018



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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 08 Apr 2021 15:18:30

Generated On: 09 Jun 2021 16:58:40

Condition	RIGHT ROTATOR CUFF TEAR
Start date (dd MMM yyyy)	UN DEC 2018
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 DEC 2018
Stop date completely unknown	False
Start Month and Year (derived)	DEC 2018
Start Year (derived)	2018
Stop Month and Year (derived)	DEC 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 08 Apr 2021 15:18:30

Generated On: 09 Jun 2021 16:58:40

Condition	RIGHT BICEP TENDON REPAIR
Start date (dd MMM yyyy)	UN DEC 2018
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 DEC 2018
Stop date completely unknown	False
Start Month and Year (derived)	DEC 2018
Start Year (derived)	2018
Stop Month and Year (derived)	DEC 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 08 Apr 2021 15:18:30

Generated On: 09 Jun 2021 16:58:40

Condition	RIGHT ROTATOR CUFF REPAIR
Start date (dd MMM yyyy)	UN DEC 2018
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 DEC 2018
Stop date completely unknown	False
Start Month and Year (derived)	DEC 2018
Start Year (derived)	2018
Stop Month and Year (derived)	DEC 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 08 Apr 2021 15:18:30

Generated On: 09 Jun 2021 16:58:40

Condition	DEVIATED SEPTUM
Start date (dd MMM yyyy)	UN UNK 1988
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 1988
Start Year (derived)	1988
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 08 Apr 2021 15:18:30

Generated On: 09 Jun 2021 16:58:40

Condition	CHOLECYSTECTOMY
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	JAN 2000
Stop Year (derived)	2000

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 08 Apr 2021 15:18:30

Generated On: 09 Jun 2021 16:58:40

Condition	DEGENERATIVE DISC DISEASE (LUMBAR)
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) 08 Apr 2021 15:18:30

Generated On: 09 Jun 2021 16:58:40

Condition	LUMBOSACRAL SPONDYLOSIS
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 (13)

Data signed: (b) (4) 08 Apr 2021 15:18:30

Generated On: 09 Jun 2021 16:58:40

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



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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 08 Apr 2021 15:18:30

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

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 08 Apr 2021 15:18:30

Generated On: 09 Jun 2021 16:58:40

Condition	CHRONIC KIDNEY DISEASE STAGE 3
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 (16)

Data signed: (b) (4) 08 Apr 2021 15:18:30

Generated On: 09 Jun 2021 16:58:40

Condition	POLYSUBSTANCE ABUSE
Start date (dd MMM yyyy)	UN UNK 2010
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 2017
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	JAN 2017
Stop Year (derived)	2017

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 08 Apr 2021 15:18:30

Generated On: 09 Jun 2021 16:58:40

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

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Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 08 Apr 2021 15:18:30

Generated On: 09 Jun 2021 16:58:40

Condition	UNSTABLE ANGINA
Start date (dd MMM yyyy)	UN UNK 2017
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 APR 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	APR 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 08 Apr 2021 15:18:30

Generated On: 09 Jun 2021 16:58:40

Condition	CHOLELITHIASIS
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	JAN 2000
Stop Year (derived)	2000

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Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) 08 Apr 2021 15:18:30

Generated On: 09 Jun 2021 16:58:40

Condition	STENT X2 LAD
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	JAN 2017
Stop Year (derived)	2017

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 21:56:40

Generated On: 09 Jun 2021 16:58:40

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	18 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	11:30 (24 HR)
Vital Signs Date and Time (derived)	18 AUG 2020 11:30
Height ( <i>xxx.x</i> )	69 in
Weight ( <i>xxx.x</i> )	213 lb
BMI ( <i>xxx.x</i> )	31.52037 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 21:56:40

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 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: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 21:56:40

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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) 15 Feb 2021 21:56:40

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 21:56:40

Generated On: 09 Jun 2021 16:58:40

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 21:56:40

Generated On: 09 Jun 2021 16:58:40

What was the date of randomization? (dd MMM yyyy) 18 AUG 2020

What was the participant's randomization number? 143852

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 21:56:40

Generated On: 09 Jun 2021 16:58:40

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 21:56:40

Generated On: 09 Jun 2021 16:58:40

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)	18 AUG 2020
Time of assessment (00:00-23:59)	11:30 (24 HR)
Vital Signs Date and Time (derived)	18 AUG 2020 11:30
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	109 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 21:56:40

Generated On: 09 Jun 2021 16:58:40

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)	18 AUG 2020
Time of assessment (00:00-23:59)	13:36 (24 HR)
Vital Signs Date and Time (derived)	18 AUG 2020 13:36
Temperature (xxx.x)	98 F
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)	155 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	102 mmHg
Diastolic Blood Pressure units	MMHG



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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 21:56:40

Generated On: 09 Jun 2021 16:58:40

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 21:56:40

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Was study treatment given? Yes ☒  
No ☐

If No, reason not given

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 18 AUG 2020

What was the treatment time? (00:00-23:59) 13:05 (24 HR)

Treatment Date and Time (derived) 18 AUG 2020 13:05

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 21:56:40

Generated On: 09 Jun 2021 16:58:40

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

18 AUG 2020

Collection time (00:00-23:59)

12:23 (24 HR)

Collection date and time (derived)

18 AUG 2020 12:23

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 21:56:40

Generated On: 09 Jun 2021 16:58:40

Collection date (dd MMM yyyy)			18 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:58	18 AUG 2020 11:58
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 21:56:40

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Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 AUG 2020 13:40

PC Open Date & Time

18 AUG 2020 13:25

PC Close Date & Time

18 AUG 2020 15:55

US3312130

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:58:40

**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 98.0 °F

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

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

PC Time Stamp	18 AUG 2020 20:59
PC Open Date & Time	18 AUG 2020 16:50
PC Close Date & Time	19 AUG 2020 11:59

US3312130

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 AUG 2020 19:22

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59



US3312130

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:58:40

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**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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

20 AUG 2020 21:42

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3312130

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 AUG 2020 21:14

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3312130

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:58:40

**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

98.6 °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

22 AUG 2020 19:25

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3312130

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:58:40

**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

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 AUG 2020 21:35

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3312130

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:58:40

**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

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 23:06

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3312130

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

18 AUG 2020 13:40

PC Open Date & Time

18 AUG 2020 13:25

PC Close Date & Time

18 AUG 2020 15:55

US3312130

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:58:40

**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

18 AUG 2020 21:00

PC Open Date & Time

18 AUG 2020 16:50

PC Close Date & Time

19 AUG 2020 11:59

US3312130

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:58:40

**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

19 AUG 2020 19:22

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59



US3312130

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:58:40

**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

20 AUG 2020 21:42

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3312130

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:58:40

**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

21 AUG 2020 21:13

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3312130

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:58:40

**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

22 AUG 2020 19:27

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3312130

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:58:40

**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

23 AUG 2020 21:36

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3312130

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:58:40

**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

24 AUG 2020 23:06

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3312130

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:58:40

**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 ☐

US3312130

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:58:40

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

No ☒

Yes ☐

PC Time stamp	18 AUG 2020 13:41
PC Open Date & Time	18 AUG 2020 13:25
PC Close Date & Time	18 AUG 2020 15:55

US3312130

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:58:40

**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 ☐



US3312130

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:58:40

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

No ☒

Yes ☐

PC Time stamp	18 AUG 2020 21:01
PC Open Date & Time	18 AUG 2020 16:50
PC Close Date & Time	19 AUG 2020 11:59

US3312130

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3312130

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:58:40

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 19:23
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3312130

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:58:40

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3312130

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:58:40

Yes <input type="checkbox"/>	
PC Time stamp	20 AUG 2020 21:42
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3312130

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:58:40

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

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EAB) (1725)

US3312130

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:58:40

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 21:14
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3312130

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:58:40

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)



US3312130

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:58:40

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 19:28
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3312130

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

DAY 6

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3312130

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:58:40

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 21:37
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3312130

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

DAY 7

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:58:40

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 23:07
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3312130

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 21:56:40

Generated On: 09 Jun 2021 16:58:40

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3312130

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 21:56:40

Generated On: 09 Jun 2021 16:58:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312130

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 21:56:40

Generated On: 09 Jun 2021 16:58:40

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3312130

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 21:56:40

Generated On: 09 Jun 2021 16:58:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312130

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 21:56:40

Generated On: 09 Jun 2021 16:58:40

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3312130

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 21:56:40

Generated On: 09 Jun 2021 16:58:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312130

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 21:56:41

Generated On: 09 Jun 2021 16:58:40

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 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

US3312130

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 21:56:41

Generated On: 09 Jun 2021 16:58:40

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)	18 SEP 2020
Time of assessment (00:00-23:59)	13:09 (24 HR)
Vital Signs Date and Time (derived)	18 SEP 2020 13:09
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	149 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	100 mmHg
Diastolic Blood Pressure units	MMHG

US3312130

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 21:56:41

Generated On: 09 Jun 2021 16:58:40

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	18 SEP 2020
Time of assessment (00:00-23:59)	14:39 (24 HR)
Vital Signs Date and Time (derived)	18 SEP 2020 14:39
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
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)	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	96 mmHg
Diastolic Blood Pressure units	MMHG

US3312130

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 21:56:41

Generated On: 09 Jun 2021 16:58:40

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 SEP 2020

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

US3312130

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 21:56:41

Generated On: 09 Jun 2021 16:58:40

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) 18 SEP 2020

What was the treatment time? (00:00-23:59) 14:08 (24 HR)

Treatment Date and Time (derived) 18 SEP 2020 14:08

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



US3312130

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 21:56:41

Generated On: 09 Jun 2021 16:58:40

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

18 SEP 2020

Collection time (00:00-23:59)

13:34 (24 HR)

Collection date and time (derived)

18 SEP 2020 13:34

US3312130

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 21:56:41

Generated On: 09 Jun 2021 16:58:40

Collection date (dd MMM yyyy)			18 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:29	18 SEP 2020 13:29
Nasopharyngeal Swab 2	No		

US3312130

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 21:56:41

Generated On: 09 Jun 2021 16:58:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312130

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 SEP 2020 14:41

PC Open Date & Time

18 SEP 2020 14:28

PC Close Date & Time

18 SEP 2020 16:58

US3312130

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.1 °F

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

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

PC Time Stamp	19 SEP 2020 03:01
PC Open Date & Time	18 SEP 2020 17:53
PC Close Date & Time	19 SEP 2020 11:59

US3312130

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

19 SEP 2020 21:23

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3312130

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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

21 SEP 2020 09:20

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3312130

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 SEP 2020 19:19

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59



US3312130

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:58:40

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**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.4 °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

23 SEP 2020 02:28

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3312130

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:58:40

---

**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

98.4 °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

23 SEP 2020 18:28

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3312130

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:58:40

---

**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

98.2 °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

25 SEP 2020 08:58

---

PC Open Date & Time

24 SEP 2020 12:00

---

PC Close Date & Time

25 SEP 2020 11:59

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US3312130

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

18 SEP 2020 14:41

PC Open Date & Time

18 SEP 2020 14:28

PC Close Date & Time

18 SEP 2020 16:58

US3312130

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:58:40

**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

19 SEP 2020 03:01

PC Open Date & Time

18 SEP 2020 17:53

PC Close Date & Time

19 SEP 2020 11:59

US3312130

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:58:40

**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

19 SEP 2020 21:24

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3312130

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:58:40

**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

21 SEP 2020 09:21

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3312130

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:58:40

**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

21 SEP 2020 19:19

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59



US3312130

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:58:40

**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

23 SEP 2020 02:29

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3312130

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:58:40

**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

23 SEP 2020 18:29

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3312130

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:58:40

**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

25 SEP 2020 08:58

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3312130

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:58:40

**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 ☐

US3312130

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:58:40

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

No ☒

Yes ☐

PC Time stamp	18 SEP 2020 14:42
PC Open Date & Time	18 SEP 2020 14:28
PC Close Date & Time	18 SEP 2020 16:58

US3312130

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:58:40

**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 ☐

US3312130

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:58:40

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

No ☒

Yes ☐

PC Time stamp	19 SEP 2020 03:01
PC Open Date & Time	18 SEP 2020 17:53
PC Close Date & Time	19 SEP 2020 11:59

US3312130

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3312130

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:58:40

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 21:25
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3312130

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:58:40

**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)

109 of 3527

US3312130

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:58:40

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 09:21
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3312130

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:58:40

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 ☒

US3312130

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:58:40

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 19:19
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3312130

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

DAY 5

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3312130

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:58:40

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 02:29
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3312130

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:58:40

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3312130

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:58:40

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 18:29
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3312130

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

DAY 7

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3312130

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:58:40

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 08:59
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3312130

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 21:56:40

Generated On: 09 Jun 2021 16:58:40

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3312130

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 21:56:40

Generated On: 09 Jun 2021 16:58:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312130

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 21:56:40

Generated On: 09 Jun 2021 16:58:40

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3312130

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 21:56:40

Generated On: 09 Jun 2021 16:58:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312130

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 21:56:40

Generated On: 09 Jun 2021 16:58:40

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 9 OCT 2020

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

Comments

*If Contact Not Made, please provide Comments*



US3312130

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 21:56:40

Generated On: 09 Jun 2021 16:58:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312130

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 21:56:41

Generated On: 09 Jun 2021 16:58:40

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 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

US3312130

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 21:56:41

Generated On: 09 Jun 2021 16:58:40

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	16 OCT 2020
Time of assessment (00:00-23:59)	12:50 (24 HR)
Vital Signs Date and Time (derived)	16 OCT 2020 12:50
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	159 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	101 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3312130

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 21:56:41

Generated On: 09 Jun 2021 16:58:40

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 OCT 2020

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

US3312130

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 21:56:41

Generated On: 09 Jun 2021 16:58:40

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

16 OCT 2020

Collection time (00:00-23:59)

13:20 (24 HR)

Collection date and time (derived)

16 OCT 2020 13:20

US3312130

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 21:56:41

Generated On: 09 Jun 2021 16:58:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312130

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 OCT 2020 00:58:51

Patient Cloud Open Date & Time

18 OCT 2020 00:01

Patient Cloud Close Date & Time

22 OCT 2020 23:59

US3312130

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

**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

25 OCT 2020 04:13:45

Patient Cloud Open Date & Time

25 OCT 2020 00:01

Patient Cloud Close Date & Time

29 OCT 2020 23:59



US3312130

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

**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

01 NOV 2020 00:01:25

Patient Cloud Open Date & Time

01 NOV 2020 00:01

Patient Cloud Close Date & Time

05 NOV 2020 23:59

US3312130

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

**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

15 NOV 2020 00:02:02

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	20 NOV 2020 10:44:38
Patient Cloud Open Date & Time	19 NOV 2020 00:01
Patient Cloud Close Date & Time	23 NOV 2020 23:59

US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 NOV 2020 03:46:14

Patient Cloud Open Date & Time

26 NOV 2020 00:01

Patient Cloud Close Date & Time

30 NOV 2020 23:59

US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

**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

03 DEC 2020 05:03:37

Patient Cloud Open Date & Time

03 DEC 2020 00:01

Patient Cloud Close Date & Time

07 DEC 2020 23:59

US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

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 <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 DEC 2020 00:35:10
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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	17 DEC 2020 04:23:36
Patient Cloud Open Date & Time	17 DEC 2020 00:01
Patient Cloud Close Date & Time	21 DEC 2020 23:59

US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 DEC 2020 00:54:12

Patient Cloud Open Date & Time

24 DEC 2020 00:01

Patient Cloud Close Date & Time

28 DEC 2020 23:59



US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

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

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

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

31 DEC 2020 00:01

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[Patient Cloud Close Date & Time](#)

04 JAN 2021 23:59

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US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

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

07 JAN 2021 00:01

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[Patient Cloud Close Date & Time](#)

11 JAN 2021 23:59

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US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

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 <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 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	14 JAN 2021 00:01:56
Patient Cloud Open Date & Time	14 JAN 2021 00:01
Patient Cloud Close Date & Time	18 JAN 2021 23:59

US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	False
Chills	False
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	True
Body aches	True
Headache	False
New loss of taste	True
New loss of smell	False
Sore throat	True
Congestion	False
Runny nose	True
Nausea	False
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"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message 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	21 JAN 2021 00:02:21
Patient Cloud Open Date & Time	21 JAN 2021 00:01
PRODUCTION RELEASE (v12.003 EAB) (1725)	
145 of 3527	

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

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[Patient Cloud Close Date & Time](#)

25 JAN 2021 23:59

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US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

**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

29 JAN 2021 06:40:34

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59



US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

**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

04 FEB 2021 00:56:14

Patient Cloud Open Date & Time

04 FEB 2021 00:01

Patient Cloud Close Date & Time

08 FEB 2021 23:59

US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 FEB 2021 03:46:11

Patient Cloud Open Date & Time

11 FEB 2021 00:01

Patient Cloud Close Date & Time

15 FEB 2021 23:59

US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

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 <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	18 FEB 2021 00:01:39
Patient Cloud Open Date & Time	18 FEB 2021 00:01
Patient Cloud Close Date & Time	22 FEB 2021 23:59

US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

**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

26 FEB 2021 19:40:54

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59

US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

**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

04 MAR 2021 06:38:02

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59

US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

**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

11 MAR 2021 02:18:05

Patient Cloud Open Date & Time

11 MAR 2021 00:01

Patient Cloud Close Date & Time

15 MAR 2021 23:59

US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

**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

18 MAR 2021 00:12:25

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

**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

25 MAR 2021 07:10:10

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59



US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

**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

01 APR 2021 00:02:32

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

**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

09 APR 2021 05:46:52

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

**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

15 APR 2021 09:38:09

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

**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

23 APR 2021 13:33:38

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 APR 2021 11:15:48

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

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

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

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

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[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

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US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

DAY 271

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐



**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

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

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[Patient Cloud Open Date & Time](#)

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13 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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17 MAY 2021 23:59

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US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

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

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[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

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US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

DAY 285

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

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

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

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

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

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

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

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

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

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

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[Patient Cloud Open Date & Time](#)

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27 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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31 MAY 2021 23:59

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US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

**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 ☐

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

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

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[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

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US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

**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 ☐



**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

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

[Patient Cloud Open Date & Time](#)

10 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

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

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 JUN 2021 23:59

US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

**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 ☐

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

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

US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

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"/>

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

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

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[Patient Cloud Open Date & Time](#)

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01 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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05 JUL 2021 23:59

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US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

**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 ☐



**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	08 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	12 JUL 2021 23:59

US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

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"/>

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

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

US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

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"/>

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	22 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 JUL 2021 23:59

US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

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

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

TIMEPOINT	DAY 355
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

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

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[Patient Cloud Open Date & Time](#)

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05 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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09 AUG 2021 23:59

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US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

**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 ☐

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

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

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[Patient Cloud Close Date & Time](#)

16 AUG 2021 23:59

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US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

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

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

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

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

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[Patient Cloud Open Date & Time](#)

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19 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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23 AUG 2021 23:59

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US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

**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 ☐

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

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

US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

DAY 383

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

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

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

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

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

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

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

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



**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

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

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[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

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US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

**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 ☐

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

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

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[Patient Cloud Open Date & Time](#)

09 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

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US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

**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 ☐

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

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

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[Patient Cloud Close Date & Time](#)

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20 SEP 2021 23:59

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US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

**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 ☐

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

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

23 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

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US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

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"/>



**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

**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 ☐

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

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

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[Patient Cloud Close Date & Time](#)

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11 OCT 2021 23:59

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US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

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

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

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

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[Patient Cloud Close Date & Time](#)

18 OCT 2021 23:59

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US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

**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°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 ☐

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

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

US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

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



**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

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

28 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

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US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

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

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[Patient Cloud Open Date & Time](#)

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04 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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08 NOV 2021 23:59

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US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

**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 ☐

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

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

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[Patient Cloud Open Date & Time](#)

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11 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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15 NOV 2021 23:59

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US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

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

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

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

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[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

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US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

**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  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

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 ☐



**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	25 NOV 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 NOV 2021 23:59
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US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

**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 ☐

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	02 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	06 DEC 2021 23:59

US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

**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 ☐

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

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

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

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

US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

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

US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

**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 ☐

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

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

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[Patient Cloud Open Date & Time](#)

30 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

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US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

**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°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 ☐

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

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

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[Patient Cloud Open Date & Time](#)

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06 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 JAN 2022 23:59

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US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

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

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

**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 ☐



**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

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

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[Patient Cloud Close Date & Time](#)

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24 JAN 2022 23:59

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US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

DAY 530

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

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

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

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

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

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

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

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

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	27 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	31 JAN 2022 23:59

US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

**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 ☐

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

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

US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

DAY 544

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

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

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[Patient Cloud Open Date & Time](#)

10 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

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US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

**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 ☐



**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

21 FEB 2022 23:59

US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

**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 ☐

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	24 FEB 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	28 FEB 2022 23:59
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US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

**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 ☐

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

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

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[Patient Cloud Open Date & Time](#)

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03 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 MAR 2022 23:59

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US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

**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°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 ☐

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

**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 ☐



**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

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

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[Patient Cloud Open Date & Time](#)

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17 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 MAR 2022 23:59

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US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

**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°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 ☐

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

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

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[Patient Cloud Open Date & Time](#)

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24 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 MAR 2022 23:59

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US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

**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 ☐

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

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

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[Patient Cloud Open Date & Time](#)

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31 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 APR 2022 23:59

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US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

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

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

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

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[Patient Cloud Close Date & Time](#)

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11 APR 2022 23:59

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US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

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



**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	14 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 APR 2022 23:59

US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

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

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

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

US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

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"/>

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

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

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[Patient Cloud Close Date & Time](#)

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02 MAY 2022 23:59

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US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

**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°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 ☐

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

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

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[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

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US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

**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 ☐



**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	12 MAY 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 MAY 2022 23:59

US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

DAY 642

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

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

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

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

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

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

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

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

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

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

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[Patient Cloud Close Date & Time](#)

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23 MAY 2022 23:59

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US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

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

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[Patient Cloud Close Date & Time](#)

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30 MAY 2022 23:59

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US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

**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 ☐

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

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

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[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

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US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

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

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[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

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US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

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

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

**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 ☐

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

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

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[Patient Cloud Open Date & Time](#)

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23 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 JUN 2022 23:59

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US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

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

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	30 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	04 JUL 2022 23:59

US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

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"/>



**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

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

[Patient Cloud Open Date & Time](#)

07 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

**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 ☐

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

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

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[Patient Cloud Close Date & Time](#)

18 JUL 2022 23:59

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US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

**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°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 ☐

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

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

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[Patient Cloud Open Date & Time](#)

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21 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 JUL 2022 23:59

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US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	28 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	01 AUG 2022 23:59

US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

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"/>



**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

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

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[Patient Cloud Open Date & Time](#)

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04 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 AUG 2022 23:59

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US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

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

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

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

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[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

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US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

**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 ☐

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

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

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[Patient Cloud Close Date & Time](#)

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22 AUG 2022 23:59

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US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

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

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	25 AUG 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 AUG 2022 23:59

US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

DAY 747

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	01 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	05 SEP 2022 23:59

US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

**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 ☐

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

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

[Patient Cloud Open Date & Time](#)

08 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 SEP 2022 23:59

US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

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

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

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

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[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

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US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

**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°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 ☐



**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

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

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

**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 ☐

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

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

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[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

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US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

**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 ☐

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

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

US3312130

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

DAY 796

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	20 OCT 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	24 OCT 2022 23:59
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US3312130

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:58:40

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 22:04:37



US3312130

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 18:16:46

Generated On: 09 Jun 2021 16:58:40

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 13 NOV 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3312130

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 18:16:46

Generated On: 09 Jun 2021 16:58:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312130

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 18:16:45

Generated On: 09 Jun 2021 16:58:40

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

OCCURRED DURING  
CONVALESCENT PERIOD.

If Contact Not Made, please provide Comments

US3312130

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 18:16:45

Generated On: 09 Jun 2021 16:58:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312130

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 18:16:45

Generated On: 09 Jun 2021 16:58:40

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3312130

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 18:16:45

Generated On: 09 Jun 2021 16:58:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312130

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 18:16:46

Generated On: 09 Jun 2021 16:58:40

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3312130

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 18:16:46

Generated On: 09 Jun 2021 16:58:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3312130

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 18:16:46

Generated On: 09 Jun 2021 16:58:40

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

Visit date (dd MMM yyyy)	05 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3312130

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 18:16:46

Generated On: 09 Jun 2021 16:58:40

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) \_\_\_\_\_

US3312130

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 18:16:46

Generated On: 09 Jun 2021 16:58:40

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.*

US3312130

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 18:16:46

Generated On: 09 Jun 2021 16:58:40

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	05 MAR 2021
Collection time (00:00-23:59)	15:20 (24 HR)
Collection date and time (derived)	05 MAR 2021 15:20

US3312130

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 18:16:46

Generated On: 09 Jun 2021 16:58:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312130

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 15:36:55

Generated On: 09 Jun 2021 16:58:40

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3312130

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 20:38:55

Generated On: 09 Jun 2021 16:58:40

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3312130

Folder: Covid-19 Assessment 15 Dec 2020

Form: COVID-19 Contact

Data signed: (b) (4) 05 Apr 2021 18:16:43

Generated On: 09 Jun 2021 16:58:40

Date of Contact	15 DEC 2020
Time of Contact	16:45
Date and Time of Contact (derived)	15 DEC 2020 16:45
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" 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>



US3312130

Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 05 Apr 2021 18:16:44

Generated On: 09 Jun 2021 16:58:40

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"/>

US3312130

Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 05 Apr 2021 18:16:44

Generated On: 09 Jun 2021 16:58:40

	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	15 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 checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input 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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EAB) (1725)

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 05 Apr 2021 18:16:44

Generated On: 09 Jun 2021 16:58:40

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input 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 type="radio"/>
	Mild	<input checked="" 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"/>

US3312130

Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 05 Apr 2021 18:16:44

Generated On: 09 Jun 2021 16:58:40

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 checked="" type="radio"/>
	Moderate	<input 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"/>

US3312130

Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 05 Apr 2021 18:16:44

Generated On: 09 Jun 2021 16:58:40

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"/>

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 05 Apr 2021 18:16:44

Generated On: 09 Jun 2021 16:58:40

	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	16 DEC 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.3 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 checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input 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"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 05 Apr 2021 18:16:44

Generated On: 09 Jun 2021 16:58:40

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input 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 type="radio"/>
	Mild	<input checked="" 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"/>

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 05 Apr 2021 18:16:44

Generated On: 09 Jun 2021 16:58:40

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 checked="" type="radio"/>
	Moderate	<input 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 15 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 05 Apr 2021 18:16:44

Generated On: 09 Jun 2021 16:58:40

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 15 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 05 Apr 2021 18:16:44

Generated On: 09 Jun 2021 16:58:40

	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	17 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	98.9 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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input 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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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 05 Apr 2021 18:16:44

Generated On: 09 Jun 2021 16:58:40

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

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 05 Apr 2021 18:16:44

Generated On: 09 Jun 2021 16:58:40

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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input 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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 05 Apr 2021 18:16:44

Generated On: 09 Jun 2021 16:58:40

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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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 05 Apr 2021 18:16:44

Generated On: 09 Jun 2021 16:58:40

	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	18 DEC 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	98.8 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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input 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"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 05 Apr 2021 18:16:44

Generated On: 09 Jun 2021 16:58:40

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

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 05 Apr 2021 18:16:44

Generated On: 09 Jun 2021 16:58:40

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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input 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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>



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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 05 Apr 2021 18:16:44

Generated On: 09 Jun 2021 16:58:40

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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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 05 Apr 2021 18:16:44

Generated On: 09 Jun 2021 16:58:40

	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	19 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.5 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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input 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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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 05 Apr 2021 18:16:44

Generated On: 09 Jun 2021 16:58:40

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

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 05 Apr 2021 18:16:44

Generated On: 09 Jun 2021 16:58:40

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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input 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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 05 Apr 2021 18:16:44

Generated On: 09 Jun 2021 16:58:40

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"/>

US3312130

Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 05 Apr 2021 18:16:44

Generated On: 09 Jun 2021 16:58:40

	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	20 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.1 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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input 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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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 05 Apr 2021 18:16:44

Generated On: 09 Jun 2021 16:58:40

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

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 05 Apr 2021 18:16:44

Generated On: 09 Jun 2021 16:58:40

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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input 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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>



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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 05 Apr 2021 18:16:44

Generated On: 09 Jun 2021 16:58:40

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"/>

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 05 Apr 2021 18:16:44

Generated On: 09 Jun 2021 16:58:40

	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	21 DEC 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.4 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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input 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 15 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 05 Apr 2021 18:16:44

Generated On: 09 Jun 2021 16:58:40

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

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 05 Apr 2021 18:16:44

Generated On: 09 Jun 2021 16:58:40

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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input 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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 05 Apr 2021 18:16:44

Generated On: 09 Jun 2021 16:58:40

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 15 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 05 Apr 2021 18:16:44

Generated On: 09 Jun 2021 16:58:40

	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	22 DEC 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input 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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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 05 Apr 2021 18:16:44

Generated On: 09 Jun 2021 16:58:40

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	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 15 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 05 Apr 2021 18:16:44

Generated On: 09 Jun 2021 16:58:40

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 15 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 05 Apr 2021 18:16:44

Generated On: 09 Jun 2021 16:58:40

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 15 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 05 Apr 2021 18:16:44

Generated On: 09 Jun 2021 16:58:40

	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	23 DEC 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.4 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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input 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"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 05 Apr 2021 18:16:44

Generated On: 09 Jun 2021 16:58:40

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

US3312130

Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 05 Apr 2021 18:16:44

Generated On: 09 Jun 2021 16:58:40

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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input 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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 05 Apr 2021 18:16:44

Generated On: 09 Jun 2021 16:58:40

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 15 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 05 Apr 2021 18:16:44

Generated On: 09 Jun 2021 16:58:40

	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	24 DEC 2020
------	-------------

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

O2 Saturation	98 %
---------------	------

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

Temperature	98.1 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 checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input 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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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 05 Apr 2021 18:16:44

Generated On: 09 Jun 2021 16:58:40

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

US3312130

Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 05 Apr 2021 18:16:44

Generated On: 09 Jun 2021 16:58:40

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input 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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input 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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>



US3312130

Folder: Covid-19 Assessment 15 Dec 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 05 Apr 2021 18:16:43

Generated On: 09 Jun 2021 16:58:40

Date of Visit	16 DEC 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of Test	16 DEC 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	1

US3312130

Folder: Covid-19 Assessment 15 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 05 Apr 2021 18:16:44

Generated On: 09 Jun 2021 16:58:40

Did the subject have Respiratory Rates  $\geq 30$  per Minute? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

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

Did the subject have Heart Rate  $\geq 125$  beats per minute? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

Heart Rate \_\_\_\_\_

Did the subject have Oxygen Saturation of SpO<sub>2</sub>  $\leq 93\%$  on room air at sea level? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

Oxygen Saturation \_\_\_\_\_

Did the subject have PaO<sub>2</sub>/FIO<sub>2</sub> Ratio  $< 300$  mm Hg? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

PaO<sub>2</sub> \_\_\_\_\_

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date \_\_\_\_\_

Did the subject have Acute Respiratory Distress Syndrome (ARDS)? Yes ☐ No ☒

Start Date \_\_\_\_\_

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 05 Apr 2021 18:16:44

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If Yes to either Did subject require any of the following:

**Ventilator Support:**

High-Flow Oxygen? Yes ☐ No ☒

Start Date

End Date

Non-Invasive Ventilation? Yes ☐ No ☒

Start Date

End Date

Mechanical Ventilation? Yes ☐ No ☒

Start Date

End Date

ECMO? Yes ☐ No ☒

Start Date

End Date

**Evidence of Shock:**

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg Yes ☐ No ☒

Start Date

End Date

Evidence of Shock Requires Vasopressors Yes ☐ No ☒

Start Date

End Date

Acute Renal Dysfunction? Yes ☐ No ☒

Start Date

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 05 Apr 2021 18:16:44

Generated On: 09 Jun 2021 16:58:40

Hepatic Dysfunction? Yes ☐  
No ☒

Start Date

Neurologic Dysfunction? Yes ☐  
No ☒

Start Date

**Evidence of Pneumonia:**

Clinical Evidence Yes ☐  
No ☐

Date of Assessment

Radiographical Evidence Yes ☐  
No ☒

Date of Assessment

Admission to an intensive care unit due to SARS-CoV-2 Yes ☐  
No ☒

Start Date

End Date

US3312130

Folder: Covid-19 Assessment 15 Dec 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 05 Apr 2021 18:16:44

Generated On: 09 Jun 2021 16:58:40

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[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

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US3312130

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 05 Apr 2021 18:16:44

Generated On: 09 Jun 2021 16:58:40

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	18 DEC 2020
Day 5	Yes	20 DEC 2020
Day 7	Yes	22 DEC 2020
Day 9	No	
Day 14	No	
Day 21	No	
Day 28	Yes	14 JAN 2021

US3312130

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 18:16:44

Generated On: 09 Jun 2021 16:58:40

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 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

US3312130

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 18:16:44

Generated On: 09 Jun 2021 16:58:40

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	16 DEC 2020
Time of assessment (00:00-23:59)	11:33 (24 HR)
Vital Signs Date and Time (derived)	16 DEC 2020 11:33
Height (xxx.x)	69 in
Weight (xxx.x)	207 lb
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	172 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	110 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



US3312130

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 18:16:44

Generated On: 09 Jun 2021 16:58:40

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 DEC 2020

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

US3312130

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 05 Apr 2021 18:16:44

Generated On: 09 Jun 2021 16:58:40

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

16 DEC 2020

US3312130

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 18:16:43

Generated On: 09 Jun 2021 16:58:40

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 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	SICKD28

US3312130

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 18:16:43

Generated On: 09 Jun 2021 16:58:40

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 JAN 2021
Time of assessment (00:00-23:59)	14:30 (24 HR)
Vital Signs Date and Time (derived)	14 JAN 2021 14:30
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	98.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	88 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	156 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	97 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3312130

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 18:16:43

Generated On: 09 Jun 2021 16:58:40

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 JAN 2021

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

US3312130

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 05 Apr 2021 18:16:43

Generated On: 09 Jun 2021 16:58:40

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

14 JAN 2021

US3312130

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

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 18:16:45

Generated On: 09 Jun 2021 16:58:40

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

Visit date (dd MMM yyyy)	05 FEB 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3312130

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

Form: Unblinding

Data signed: (b) (4) 05 Apr 2021 18:16:45

Generated On: 09 Jun 2021 16:58:40

Date of updated informed consent ( <i>dd MMM yyyy</i> )	05 FEB 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding ( <i>dd MMM yyyy</i> )	05 FEB 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1



US3312130

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 05 Apr 2021 18:16:45

Generated On: 09 Jun 2021 16:58:40

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3312130

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Apr 2021 18:16:45

Generated On: 09 Jun 2021 16:58:40

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	05 MAR 2021
Time of assessment (00:00-23:59)	14:34 (24 HR)
Vital Signs Date and Time (derived)	05 MAR 2021 14:34
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	143 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	98 mmHg
Diastolic Blood Pressure units	MMHG

US3312130

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Apr 2021 18:16:45

Generated On: 09 Jun 2021 16:58:40

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	05 MAR 2021
Time of assessment (00:00-23:59)	16:00 (24 HR)
Vital Signs Date and Time (derived)	05 MAR 2021 16:00
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG

US3312130

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

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 18:16:45

Generated On: 09 Jun 2021 16:58:40

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Was the physical examination performed?

Yes ☒

No ☐

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Date of examination (dd MMM yyyy)

05 MAR 2021

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

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US3312130

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

Form: Exposure

Data signed: (b) (4) 05 Apr 2021 18:16:45

Generated On: 09 Jun 2021 16:58:40

Was study treatment given? Yes ☒  
No ☐

If No, reason not given

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

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

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

What was the treatment date? (dd MMM yyyy) 05 MAR 2021

What was the treatment time? (00:00-23:59) 15:29 (24 HR)

Treatment Date and Time (derived) 05 MAR 2021 15:29

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

US3312130

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 18:16:45

Generated On: 09 Jun 2021 16:58:40

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	05 FEB 2021
Collection time (00:00-23:59)	11:38 (24 HR)
Collection date and time (derived)	05 FEB 2021 11:38

US3312130

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 05 Apr 2021 18:16:45

Generated On: 09 Jun 2021 16:58:40

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	05 FEB 2021
Collection time (00:00 - 23:59)	11:37
Collection Date and Time (derived)	05 FEB 2021 11:37

US3312130

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

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 18:16:45

Generated On: 09 Jun 2021 16:58:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3312130

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 18:16:46

Generated On: 09 Jun 2021 16:58:40

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3312130

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 18:16:46

Generated On: 09 Jun 2021 16:58:40

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

US3312130

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 18:16:44

Generated On: 09 Jun 2021 16:58:40

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3312130

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Apr 2021 18:16:44

Generated On: 09 Jun 2021 16:58:40

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)	02 APR 2021
Time of assessment (00:00-23:59)	08:33 (24 HR)
Vital Signs Date and Time (derived)	02 APR 2021 08:33
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3312130

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Apr 2021 18:16:44

Generated On: 09 Jun 2021 16:58:40

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)	02 APR 2021
Time of assessment (00:00-23:59)	09:39 (24 HR)
Vital Signs Date and Time (derived)	02 APR 2021 09:39
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	75 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)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3312130

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 18:16:44

Generated On: 09 Jun 2021 16:58:40

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

02 APR 2021

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

US3312130

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 05 Apr 2021 18:16:44

Generated On: 09 Jun 2021 16:58:40

Was study treatment given? Yes ☒  
No ☐

If No, reason not given

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

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

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

What was the treatment date? (dd MMM yyyy) 2 APR 2021

What was the treatment time? (00:00-23:59) 09:08 (24 HR)

Treatment Date and Time (derived) 2 APR 2021 09:08

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

US3312130

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 18:16:44

Generated On: 09 Jun 2021 16:58:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3312130

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Apr 2021 19:55:19

Generated On: 09 Jun 2021 16:58:40

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3312130

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 15 Apr 2021 19:55:19

Generated On: 09 Jun 2021 16:58:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312130

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 15:36:55

Generated On: 09 Jun 2021 16:58:40

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	27 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3312130

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 29 Apr 2021 15:36:55

Generated On: 09 Jun 2021 16:58:40

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) \_\_\_\_\_

US3312130

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Apr 2021 15:36:55

Generated On: 09 Jun 2021 16:58:40

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.*

US3312130

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Apr 2021 15:36:55

Generated On: 09 Jun 2021 16:58:40

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	27 APR 2021
Collection time (00:00-23:59)	11:32 (24 HR)
Collection date and time (derived)	27 APR 2021 11:32

US3312130

Folder: Unscheduled 15 Sep 2020

Form: Unscheduled Visit Assessment

Data signed: (b) (4) 05 Apr 2021 18:16:46

Generated On: 09 Jun 2021 16:58:40

Visit Date	15 SEP 2020
Please check all assessments that apply for this visit	
Physical Exam	False
Vital Signs	True
Immunogenicity Assessment	False
Pregnancy Test	False

US3312130

Folder: Unscheduled 15 Sep 2020

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 18:16:46

Generated On: 09 Jun 2021 16:58:40

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	15 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	13:55 (24 HR)
Vital Signs Date and Time (derived)	15 SEP 2020 13:55
Temperature ( <i>xxx.x</i> )	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	70 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	172 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	122 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



US3312130

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Mar 2021 15:47:20

Generated On: 09 Jun 2021 16:58:40

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Did the participant experience any adverse events?

Yes ☒

No ☐

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If Yes, enter details on the Adverse Events form.

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US3312130

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 15:57:38

Generated On: 09 Jun 2021 16:58:40

AEID	
Adverse event	ELEVATED SYSTOLIC BLOOD PRESSURE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	16 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

US3312130

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 15:57:38

Generated On: 09 Jun 2021 16:58:40

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

US3312130

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 09 Apr 2021 15:57:38

Generated On: 09 Jun 2021 16:58:40

AEID	USA-US300-2020-MRNA-1273-P30 1000022
Adverse event	CHEST PAIN (CARDIAC RELATED)
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)	15 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)	18 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 checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	16 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	18 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 (2)

Data signed: (b) (4) 09 Apr 2021 15:57:38

Generated On: 09 Jun 2021 16:58:40

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 (2)

Data signed: (b) (4) 09 Apr 2021 15:57:38

Generated On: 09 Jun 2021 16:58:40

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SUBJECT IS HISTORIAN.NO  
DOCUMENTS AT THIS TIME TO  
CONFIRM THE FACTS OF THIS  
SAE.50 YR OLD HYPERTENSIVE  
MALE DIABETIC,  
VASCULOPATH(HISTORY OF  
CAD, ANGIOPLASTY 2017) S/P  
DOSE 1 ON 08/18/20, DOSE 2 ON  
09/18/20, WHO ON  
12/15/20EVENING CALLED TO  
REPORT ONSET IN AM OF  
HEADACHE, SUBJECTIVE  
FEVER, FATIGUE, MYALGIA,  
DIARRHEA,SORE THROAT,  
LEFT OTALGIA,RHINORRHEA,  
DIMINISHED  
TASTE,CONFUSION, MILD  
SHORTNESS OF AIR. HE  
REPORTED THAT SYMPTOMS  
DID NOT RESEMBLE PAST  
HISTORY OF ANGINA. HE  
DENIED COUGH, WHEEZING,  
EMESIS,AND WAS  
ALERT,ORIENTED AND  
APPROPRIATE ON THE  
PHONE.SUBJECT STATED HE  
REPORTED CONFUSION TO  
MEAN THAT HE WAS UNDER A  
GREAT DEAL OF STRESS AND  
NOW WITH THESE SYMPTOMS  
"I'M NOT SURE WHAT TO DO."  
WAS INSTRUCTED TO TAKE  
TYLENOL AND TO CALL SITE  
AND VISIT ER IF NO  
IMPROVEMENT OR

US3312130

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 09 Apr 2021 15:57:38

Generated On: 09 Jun 2021 16:58:40

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WORSENING OF SYMPTOMS,  
BUT OTHERWISE VISIT SITE  
FOR ILLNESS VISIT THE NEXT  
MORNING. ILLNESS VISIT AT  
SITE12/16/20 REPORTED  
SYMPTOMS PERSISTED AND HE  
ADDED COUGH TO LIST. WAS  
FOUND TO HAVE A G3  
BP175/115. HISTORY OF HIGH BP  
WHEN UNDER DURESS AND  
WHEN HAVING NOT TAKEN HIS  
BP MEDS, WHICH WAS THE  
CASE AT ILLNESS VISIT. HR  
WAS 79, RESP 14, TEMP 98.3 (NO  
ANTIPYRETICS IN PRECEDING 6  
HOURS), O2SAT WAS  
99%. PHYSICAL EXAM WAS  
NORMAL INCLUDING ABSENCE  
OF COUGH, EXCEPT SUBJECT  
SEEMED TO BE UNDER DURESS  
AND WAS AGITATED BY  
DISCUSSION WITH PROVIDERS  
REGARDING HIS BLOOD  
PRESSURE AND BECAUSE HE  
WAS ADVISED TO NOT WORK  
DUE TO PROBABILITY OF  
HAVING COVID. SUBJECT  
CALLED SITE12/17/20 TO  
REPORT THAT PREVIOUS  
NIGHT HE CONTINUED TO FEEL  
ILL WHILE AT WORK AND  
COULD NOT PERFORM THE  
HEAVY LIFTING THAT WAS  
BEING ASKED OF HIM, SO HE  
WENT TO ER. AT HOSPITAL HE

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 09 Apr 2021 15:57:38

Generated On: 09 Jun 2021 16:58:40

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WAS ADMITTED FOR  
UNCONTROLLED DIABETES  
AND HYPERTENSION WITH  
FINGERSTICK GLUCOSE > 600  
AND BP 194/105.SUBJECT IS NOT  
IN ICU AND REPORTS THAT HIS  
DOCTORS HAVE PLANS TO  
RELEASE HIM TOMORROW  
WITH NO PLANS FOR ANY  
SPECIAL OR INVASIVE  
PROCEDURES.WILL PROCURE  
MEDICAL RECORDS.SAE OF  
DIABETES EXACERBATION  
NOT RELATED TO IP,POSSIBLY  
RELATED TO COVID. FOLLOW  
UP CONTINUED IN SOURCE

---

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

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US3312130

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 09 Apr 2021 15:57:38

Generated On: 09 Jun 2021 16:58:40

AEID	USA-US300-2020-MRNA-1273-P30 1000022
Adverse event	SYMPTOMATIC COVID 19
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	15 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)	25 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 checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 09 Apr 2021 15:57:38

Generated On: 09 Jun 2021 16:58:40

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	

US3312130

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 09 Apr 2021 15:57:38

Generated On: 09 Jun 2021 16:58:40

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SUBJECT PRESENTED TO ER IN  
PM 16DEC20 WITH  
COMPLAINTS OF CHEST PAIN  
OF TIGHTNESS QUALITY AND  
UP TO 9 OUT OF 10 INTENSITY  
WHILE LIFTING BOXES, MILD  
SHORTNESS OF AIR WHEN  
BREATHING COLD AIR,  
FATIGUE, HEADACHE, AND  
DIZZINESS, WITHOUT NAUSEA,  
EMESIS, DIAPHORESIS. HE WAS  
UNSURE IF PAIN WAS SIMILAR  
TO ANGINA THAT LED TO  
CORONARY STENTING IN 2017.  
ROS WAS OTHERWISE  
NEGATIVE. PHYSICAL EXAM  
NORMAL. BP 173/106, O2SAT  
98% ON RA, GLUCOSE 629.  
SUBJECT WAS ADMITTED FOR  
CHEST PAIN WITH  
UNCONTROLLED DIABETES  
AND HYPERTENSION. HE WAS  
TREATED WITH  
NITROGLYCERIN, INSULIN AND  
RESUMPTION OF HOME MEDS  
(SUBJECT AGREED HE WAS  
NON-COMPLIANT.) MI WAS  
RULED OUT PER NSR EKG AND  
NORMAL TROPONINS X 3.  
ECHO SHOWED 50-55% EF WITH  
MILD DIASTOLIC  
DYSFUNCTION AND SEPTAL  
LVH. CXR WAS NORMAL. A  
MILD HYPONATREMIA AND  
ELEVATED CREATININE

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 09 Apr 2021 15:57:38

Generated On: 09 Jun 2021 16:58:40

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CORRECTED WITH GLUCOSE  
CONTROL AND FLUIDS.  
KETONES WERE NORMAL.  
SUBJECT AGREED TO DISTANT  
POLYSUBSTANCE ABUSE ISSUE  
AND UDS WAS NEGATIVE.  
COVID RT-PCR WAS POSITIVE.  
AFTER IMPROVEMENT IN  
SYMPTOMS, CORRECTION OF  
GLUCOSE TO 130'S AND BP TO  
140'S SUBJECT WAS  
DISCHARGED ON 18DEC20  
WITH PLAN OF CONTINUING  
WITH HUMULIN NR INSULIN,  
RESUMPTION OF HOME MEDS,  
FOLLOW-UPS WITH PCP AND  
CARDIOLOGIST AND POSSIBLE  
STRESS TEST AS OUTPATIENT.  
SUBJECT HOSPITALIZED FOR  
CHEST PAIN WITH  
UNCONTROLLED DIABETES  
AND HYPERTENSION DUE TO  
NONCOMPLIANCE, NR TO IP.  
(SEE SEPARATE SAE) COVID  
PCR IS POSITIVE BUT  
INCIDENTAL TO THIS SAE;  
COVID-19 IS NOT THE CAUSE  
OF THIS HOSPITALIZATION;  
THEREFORE, IS NOT AN SAE IN  
ITSELF

---

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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US3312130

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 09 Apr 2021 15:57:38

Generated On: 09 Jun 2021 16:58:40

AEID	USA-US300-2020-MRNA-1273-P30 1000022
Adverse event	UNCONTROLLED DIABETES MELLITUS II
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	16 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)	18 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 checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	16 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	18 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 (4)

Data signed: (b) (4) 09 Apr 2021 15:57:38

Generated On: 09 Jun 2021 16:58:40

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	SEE SAE # 2 (SPLIT PER QUERY)
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

US3312130

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 09 Apr 2021 15:57:38

Generated On: 09 Jun 2021 16:58:40

AEID	USA-US300-2020-MRNA-1273-P30 1000022
Adverse event	UNCONTROLLED HYPERTENSION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	16 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)	18 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 checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	16 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	18 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 (5)

Data signed: (b) (4) 09 Apr 2021 15:57:38

Generated On: 09 Jun 2021 16:58:40

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	SEE SAE NARRATIVE AE #2 (SPLIT PER QUERY)
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0



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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 09 Apr 2021 15:57:38

Generated On: 09 Jun 2021 16:58:40

AEID	USA-US300-2021-MRNA-1273-P30 1000015
Adverse event	ANGINA
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)	10 FEB 2021
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)	13 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	11 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	13 FEB 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 09 Apr 2021 15:57:38

Generated On: 09 Jun 2021 16:58:40

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

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ON 05FEB2021 SUBJECT WAS AT  
SITE FOR OPEN LABEL VISIT  
WHICH WAS NOT COMPLETED  
BECAUSE OF BP 175/132 AND  
IRREGULAR PULSE ON EXAM.  
HE WAS ASYMPTOMATIC. AT  
THAT TIME SUBJECT STATED  
THAT HE HAD ARRANGED TO  
SEE HIS PCP OR CARDIOLOGIST  
AT LOCAL HOSPITAL  
IMMEDIATELY. INSTEAD HE  
WENT TO THE SUPERBOWL IN  
FLORIDA. AT PHONE CALL  
16FEB21 SUBJECT REPORTED  
ANGINA 11FEB21 FOR WHICH  
HE VISITED ER. HE WAS  
ADMITTED AND A CORONARY  
STENT WAS PLACED 12FEB21.  
SUBJECT WAS DISCHARGED  
13FEB21 ON ATORVASTATIN,  
CLOPIDOGREL, AND  
ISOSORBIDE MONONITRATE AS  
NEW MEDS. HE STATED HIS  
POST-STENT BP'S WERE IN THE  
130'S/80'S. WILL PROCURE  
MEDICAL  
RECORDS.UPDATE:03/09/21MED  
RECORDS REVIEWED.SUBJ HAS  
KNOWN H/O CORONARY  
ARTERY DISEASE AND STENT  
X2 TO LAD IN 2017 WHO HAD  
ONSET OF CHEST PAIN  
STARTING 2/10/2021 AT APPROX  
20:00.HE PRESENTED TO ER ON  
2/11/2021 AND WAS

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SUBSEQUENTLY ADMITTED  
WITH UNSTABLE ANGINA. HE  
UNDERWENT PCI WITH PTCA  
AND STENT PLACEMENT ON  
2/12/2021 BEFORE LEAVING  
AGAINST MEDICAL ADVICE ON  
2/13/2021. WAS HYPERTENSIVE  
ON PRESENTATION (185/103) TO  
ER WITH LAST INPATIENT BP  
OF 140/97. EKG SHOWED NSR,  
RATE OF 73 WITHOUT ACUTE  
ST WAVE  
ABNORMALITY. TROPONIN  
LEVELS REMAINED  
<0.01 NG/ML. CXR SHOWED  
VASCULAR CALCIFICATIONS  
PRESENT IN MEDIASTINUM  
(CONSISTENT WITH KNOWN  
H/O CAD) AND DEGENERATIVE  
CHANGES OF THORACIC SPINE  
(KNOWN H/O DJD OF LUMBAR  
SPINE) BUT WAS OTHERWISE  
NORMAL. CARDIAC PET STRESS  
(2/12/21) WITH ABNORMAL  
MYOCARDIAL PERFUSION  
SCAN SHOWING MODERATE  
SIZED, MODERATE IN  
SEVERITY MOSTLY  
REVERSIBLE DEFECT  
CONSISTENT WITH ISCHEMIA  
IN ANTERIOR WALL IN  
TERRITORY TYPICAL OF LAD,  
MODERATE CORONARY  
ARTERY CALCIFICATION.  
TREATED WITH ASPIRIN PO

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AND NITROGLYCERIN SL IN ER  
ON 2/11/21.ON 2/12/21, HE  
UNDERWENT CARDIAC  
CATHETERIZATION AND PCI  
WAS PERFORMED WITH PTCA  
FOLLOWED BY STENTING OF  
THE MID TO DISTAL LAD IN  
OVERLAPPING FASHION WITH  
A MORE DISTAL LAD  
DRUG-ELUTING STENT,  
BIVALIRUDIN BOLUS  
FOLLOWED BY INFUSION WAS  
ADMINISTERED; NO  
COMPLICATIONS.HE WILL  
CONTINUE TO FOLLOW-UP  
WITH CARDIOLOGY

---

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

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 09 Apr 2021 15:57:38

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AEID

Adverse event

HYPONATREMIA

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)

16 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)

18 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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Form: Adverse Events (7)

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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	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 09 Apr 2021 15:57:38

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AEID	
Adverse event	CALCIFIED GRANULOMA LEFT MID LUNG
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	16 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Form: Adverse Events (8)

Data signed: (b) (4) 09 Apr 2021 15:57:38

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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	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 09 Apr 2021 15:57:38

Generated On: 09 Jun 2021 16:58:40

AEID

Adverse event

WORSENING OF ACUTE  
KIDNEY INJURY

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)

16 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)

17 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 ☐

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Form: Adverse Events (9)

Data signed: (b) (4) 09 Apr 2021 15:57:38

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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)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 09 Apr 2021 15:57:38

Generated On: 09 Jun 2021 16:58:40

AEID	
Adverse event	IRREGULAR HEARTBEAT
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	05 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Form: Adverse Events (10)

Data signed: (b) (4) 09 Apr 2021 15:57:38

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

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Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 09 Apr 2021 15:57:38

Generated On: 09 Jun 2021 16:58:40

AEID	
Adverse event	THORACIC SPINE DEGENERATIVE CHANGES
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)	11 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 09 Apr 2021 15:57:38

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 05 Apr 2021 18:16:43

Generated On: 09 Jun 2021 16:58:40

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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) 09 Apr 2021 16:55:53

Generated On: 09 Jun 2021 16:58:40

Name of Medication ACETYLSALICYLIC ACID

Prophylaxis Yes ☐  
No ☒

Indication CORONARY ARTERY DISEASE

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 (1)

Data signed: (b) (4) 09 Apr 2021 16:55:53

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	13 NOV 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	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) 09 Apr 2021 16:55:53

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Name of Medication COREG

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 12

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 16:55:53

Generated On: 09 Jun 2021 16:58:40

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		13 NOV 2017
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		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 (3)

Data signed: (b) (4) 09 Apr 2021 16:55:53

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Name of Medication GLIPIZIDE

Prophylaxis Yes ☐  
No ☒

Indication DIABETES MELLITUS TYPE II

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 (3)

Data signed: (b) (4) 09 Apr 2021 16:55:53

Generated On: 09 Jun 2021 16:58:40

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 JAN 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	11 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 16:55:53

Generated On: 09 Jun 2021 16:58:40

Name of Medication METFORMIN

Prophylaxis Yes ☐  
No ☒

Indication DIABETES MELLITUS TYPE II

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 16:55:53

Generated On: 09 Jun 2021 16:58:40

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		13 NOV 2017
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 16:55:53

Generated On: 09 Jun 2021 16:58:40

Name of Medication FA VXIGA

Prophylaxis Yes ☐  
No ☒

Indication DIABETES MELLITUS TYPE II

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 16:55:53

Generated On: 09 Jun 2021 16:58:40

	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)		19 FEB 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		11 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Apr 2021 16:55:53

Generated On: 09 Jun 2021 16:58:40

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐  
No ☒

Indication SYMPTOMATIC COVID-19

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Apr 2021 16:55:53

Generated On: 09 Jun 2021 16:58:40

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		15 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)		25 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 (7)

Data signed: (b) (4) 09 Apr 2021 16:55:53

Generated On: 09 Jun 2021 16:58:40

Name of Medication DEXTROSE 10 % IN WATER

Prophylaxis Yes ☐  
No ☒

Indication ACUTE KIDNEY INJURY ON  
CHRONIC KIDNEY DISEASE

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 09 Apr 2021 16:55:53

Generated On: 09 Jun 2021 16:58:40

	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 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)	16 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)		18 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 (8)

Data signed: (b) (4) 09 Apr 2021 16:55:53

Generated On: 09 Jun 2021 16:58:40

Name of Medication 0.5 NORMAL SALINE WITH  
INSULIN 100 UNITS

Prophylaxis Yes ☐  
No ☒

Indication UNTREATED DIABETES

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 09 Apr 2021 16:55:53

Generated On: 09 Jun 2021 16:58:40

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	16 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)	17 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 (9)

Data signed: (b) (4) 09 Apr 2021 16:55:53

Generated On: 09 Jun 2021 16:58:40

Name of Medication NITROGLYCERINE

Prophylaxis Yes ☐  
No ☒

Indication CHEST PAIN - CARDIAC  
RELATED

Dose per administration 5/20

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 (9)

Data signed: (b) (4) 09 Apr 2021 16:55:53

Generated On: 09 Jun 2021 16:58:40

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	16 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)		17 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 (10)

Data signed: (b) (4) 09 Apr 2021 16:55:53

Generated On: 09 Jun 2021 16:58:40

Name of Medication ASPIRIN

Prophylaxis Yes ☐  
No ☒

Indication CHEST PAIN

Dose per administration 325

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 09 Apr 2021 16:55:53

Generated On: 09 Jun 2021 16:58:40

	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)	16 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)		17 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 (11)

Data signed: (b) (4) 09 Apr 2021 16:55:53

Generated On: 09 Jun 2021 16:58:40

Name of Medication LABETOLOL

Prophylaxis Yes ☐  
No ☒

Indication UNCONTROLLED  
HYPERTENSION

Dose per administration UNK

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 (11)

Data signed: (b) (4) 09 Apr 2021 16:55:53

Generated On: 09 Jun 2021 16:58:40

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	16 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)		16 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 (12)

Data signed: (b) (4) 09 Apr 2021 16:55:53

Generated On: 09 Jun 2021 16:58:40

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐  
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 80

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 09 Apr 2021 16:55:53

Generated On: 09 Jun 2021 16:58:40

	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)	12 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 09 Apr 2021 16:55:53

Generated On: 09 Jun 2021 16:58:40

Name of Medication CLOPIDOGRAL

Prophylaxis Yes ☐  
No ☒

Indication THROMBUS PROPHYLAXIS

Dose per administration 75

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) 09 Apr 2021 16:55:53

Generated On: 09 Jun 2021 16:58:40

	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)	12 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 09 Apr 2021 16:55:53

Generated On: 09 Jun 2021 16:58:40

Name of Medication ISOSORBIDE MONONITRATE

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENTION

Dose per administration 30

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 09 Apr 2021 16:55:53

Generated On: 09 Jun 2021 16:58:40

	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)	12 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 09 Apr 2021 16:55:53

Generated On: 09 Jun 2021 16:58:40

Name of Medication ASPIRIN

Prophylaxis Yes ☐  
No ☒

Indication UNSTABLE ANGINA

Dose per administration 325

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 09 Apr 2021 16:55:53

Generated On: 09 Jun 2021 16:58:40

	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)	11 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 11 FEB 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 09 Apr 2021 16:55:53

Generated On: 09 Jun 2021 16:58:40

Name of Medication NITROGLYCERIN

Prophylaxis Yes ☐  
No ☒

Indication UNSTABLE ANGINA

Dose per administration 0.4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 09 Apr 2021 16:55:53

Generated On: 09 Jun 2021 16:58:40

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	SUBLINGUAL	
Start date (dd MMM yyyy)	11 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	11 FEB 2021	
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 (17)

Data signed: (b) (4) 09 Apr 2021 16:55:53

Generated On: 09 Jun 2021 16:58:40

Name of Medication BIVALIRUDIN

Prophylaxis Yes ☐  
No ☒

Indication UNSTABLE ANGINA

Dose per administration UNK

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 (17)

Data signed: (b) (4) 09 Apr 2021 16:55:53

Generated On: 09 Jun 2021 16:58:40

	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 checked="" type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		12 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		12 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 09 Apr 2021 16:55:53

Generated On: 09 Jun 2021 16:58:40

Name of Medication METOPROLOL

Prophylaxis Yes ☐  
No ☒

Indication UNSTABLE ANGINA

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 (18)

Data signed: (b) (4) 09 Apr 2021 16:55:53

Generated On: 09 Jun 2021 16:58:40

	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)		11 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		13 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 09 Apr 2021 16:55:53

Generated On: 09 Jun 2021 16:58:40

Name of Medication CLONIDINE

Prophylaxis Yes ☐  
No ☒

Indication UNSTABLE ANGINA

Dose per administration 0.2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 09 Apr 2021 16:55:53

Generated On: 09 Jun 2021 16:58:40

	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)		11 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 13 FEB 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 09 Apr 2021 16:55:53

Generated On: 09 Jun 2021 16:58:40

Name of Medication LISINOPRIL

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENTION

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 09 Apr 2021 16:55:53

Generated On: 09 Jun 2021 16:58:40

	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)	11 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 09 Apr 2021 16:55:53

Generated On: 09 Jun 2021 16:58:40

Name of Medication PROMETHAZINE

Prophylaxis Yes ☐  
No ☒

Indication UNSTABLE ANGINA

Dose per administration 12.5

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 (21)

Data signed: (b) (4) 09 Apr 2021 16:55:53

Generated On: 09 Jun 2021 16:58:40

	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)		11 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		13 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 09 Apr 2021 16:55:53

Generated On: 09 Jun 2021 16:58:40

Name of Medication PROMETHAZINE

Prophylaxis Yes ☐  
No ☒

Indication UNSTABLE ANGINA

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 09 Apr 2021 16:55:53

Generated On: 09 Jun 2021 16:58:40

	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)	11 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy) 13 FEB 2021		
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 09 Apr 2021 16:55:53

Generated On: 09 Jun 2021 16:58:40

Name of Medication ONDANSETRON

Prophylaxis Yes ☐  
No ☒

Indication UNSTABLE ANGINA

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 09 Apr 2021 16:55:53

Generated On: 09 Jun 2021 16:58:40

	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)		11 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		13 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 09 Apr 2021 16:55:53

Generated On: 09 Jun 2021 16:58:40

Name of Medication VICTOZA

Prophylaxis Yes ☐  
No ☒

Indication DIABETES MELLITUS TYPE II

Dose per administration 0.6

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 (24)

Data signed: (b) (4) 09 Apr 2021 16:55:53

Generated On: 09 Jun 2021 16:58:40

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	10 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



US3312130

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 05 Apr 2021 18:16:43

Generated On: 09 Jun 2021 16:58:40

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3312130

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 05 Apr 2021 18:16:43

Generated On: 09 Jun 2021 16:58:40

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
12 FEB 2021	CORONARY STENT PLACEMENT	Adverse Event	

US3312130

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:58:40

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent  
by participant, Protocol deviation, or Other, specify

US3312130

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:58:40

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 ☐

US3312130

Folder: SAE USA-US300-2020-MRNA-1273-P301000022

Form: Safety Report Form

Data signed: (b) (4) 09 Apr 2021 15:57:39

Generated On: 09 Jun 2021 16:58:40

SAEID	USA-US300-2020-MRNA-1273-P301000022
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	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3312130

Folder: SAE USA-US300-2020-MRNA-1273-P301000022

Form: Safety Report Form (1)

Data signed: (b) (4) 09 Apr 2021 15:57:39

Generated On: 09 Jun 2021 16:58:40

SAEID	USA-US300-2020-MRNA-1273-P301000022
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	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	18/DEC/2020 13:47
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

US3312130

Folder: SAE USA-US300-2020-MRNA-1273-P301000022

Form: Safety Report Form (2)

Data signed: (b) (4) 09 Apr 2021 15:57:39

Generated On: 09 Jun 2021 16:58:40

SAEID	USA-US300-2020-MRNA-1273-P301000022
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	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	22/DEC/2020 19:51
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

US3312130

Folder: SAE USA-US300-2020-MRNA-1273-P301000022

Form: Safety Report Form (3)

Data signed: (b) (4) 09 Apr 2021 15:57:39

Generated On: 09 Jun 2021 16:58:40

SAEID	USA-US300-2020-MRNA-1273-P301000022
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	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	22/JAN/2021 12:05
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



US3312130

Folder: SAE USA-US300-2020-MRNA-1273-P301000022

Form: Safety Report Form (4)

Data signed: (b) (4) 09 Apr 2021 15:57:39

Generated On: 09 Jun 2021 16:58:40

SAEID	USA-US300-2020-MRNA-1273-P301000022
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	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	18/FEB/2021 10:53
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

US3312130

Folder: SAE USA-US300-2020-MRNA-1273-P301000022

Form: Safety Report Form (5)

Data signed: (b) (4) 09 Apr 2021 15:57:39

Generated On: 09 Jun 2021 16:58:40

SAEID	USA-US300-2020-MRNA-1273-P301000022
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	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	09/APR/2021 10:45
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

US3312130

Folder: SAE USA-US300-2021-MRNA-1273-P301000015

Form: Safety Report Form

Data signed: (b) (4) 05 Apr 2021 18:16:45

Generated On: 09 Jun 2021 16:58:40

SAEID	USA-US300-2021-MRNA-1273-P301000015
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	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6

US3312130

Folder: SAE USA-US300-2021-MRNA-1273-P301000015

Form: Safety Report Form (1)

Data signed: (b) (4) 05 Apr 2021 18:16:45

Generated On: 09 Jun 2021 16:58:40

SAEID	USA-US300-2021-MRNA-1273-P301000015
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	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	18/FEB/2021 12:55
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3312130

Folder: SAE USA-US300-2021-MRNA-1273-P301000015

Form: Safety Report Form (2)

Data signed: (b) (4) 05 Apr 2021 18:16:45

Generated On: 09 Jun 2021 16:58:40

SAEID	USA-US300-2021-MRNA-1273-P301000015
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	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	08/MAR/2021 11:30
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

US3312130

Folder: SAE USA-US300-2021-MRNA-1273-P301000015

Form: Safety Report Form (3)

Data signed: (b) (4) 05 Apr 2021 18:16:45

Generated On: 09 Jun 2021 16:58:40

SAEID	USA-US300-2021-MRNA-1273-P301000015
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	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	10/MAR/2021 09:55
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3312130

Folder: SAE USA-US300-2021-MRNA-1273-P301000015

Form: Safety Report Form (4)

Data signed: (b) (4) 05 Apr 2021 18:16:45

Generated On: 09 Jun 2021 16:58:40

SAEID	USA-US300-2021-MRNA-1273-P301000015
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	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	11/MAR/2021 07:46
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

US3312130

Folder: SAE USA-US300-2021-MRNA-1273-P301000015

Form: Safety Report Form (5)

Data signed: (b) (4) 05 Apr 2021 18:16:45

Generated On: 09 Jun 2021 16:58:40

SAEID	USA-US300-2021-MRNA-1273-P301000015
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	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	18/MAR/2021 10:22
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



US3312130

Folder: SAE USA-US300-2021-MRNA-1273-P301000015

Form: Safety Report Form (6)

Data signed: (b) (4) 05 Apr 2021 18:16:45

Generated On: 09 Jun 2021 16:58:40

SAEID	USA-US300-2021-MRNA-1273-P301000015
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	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	19/MAR/2021 08:53
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

US3312130 (Prod: Johnson County Clin-Trials)

**US3312130**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 16:58:40**

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:01:42
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'US3312130'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	18 Aug 2020 16:14:23

**US3312130**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:40**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:38:27
User entered 'Yes (Y)'	Christa Estrada (b) (4) (b) (4)	18 Aug 2020 18:13:21

**US3312130**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:40**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:38:27
User entered '18 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	18 Aug 2020 16:14:24

**US3312130**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:40**

[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 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:38:27
User entered 'Clinic (Clinic)'	Christa Estrada (b) (4) (b) (4)	18 Aug 2020 18:13:21

**US3312130**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:40**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered 'SCRN'	System	18 Aug 2020 18:13:21

US3312130

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:58:40

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:38:43
User entered (b) (6) 1970'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	18 Aug 2020 16:14:25



**US3312130**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:58:40**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:38:43
User entered '50'	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:05:14

**US3312130**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:58:40**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered 'YEARS'	System	21 Aug 2020 19:05:14

**US3312130**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:58:40**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered '50'	System	18 Aug 2020 18:13:33

**US3312130**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:58:40**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:38:43
User entered 'Male (M)'	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:05:14

**US3312130**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:58:40**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:38:43
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:05:14

**US3312130**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:58:40**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:38:43
User entered 'I'	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:05:14

**US3312130**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:58:40**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:38:43
User entered '0'	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:05:14

**US3312130**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:58:40**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:38:43
User entered '0'	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:05:14



**US3312130**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:58:40**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:38:43
User entered '0'	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:05:14

**US3312130**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:58:40**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:38:43
User entered '0'	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:05:14

**US3312130**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:58:40**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:38:43
User entered '0'	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:05:14

**US3312130**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:58:40**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:38:43
User entered empty.	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:05:14

**US3312130**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:58:40**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:38:43
User entered '0'	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:05:14

**US3312130**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:58:40**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:38:43
User entered '0'	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:05:14

**US3312130**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:58:40**

**Date of Informed Consent** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:38:53
User entered '18 Aug 2020'	Christa Estrada (b) (4) (b) (4)	18 Aug 2020 18:13:33

**US3312130**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:58:40**

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered 'Aug 2020'	System	18 Aug 2020 18:13:33



**US3312130**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:58:40**

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered '2020'	System	18 Aug 2020 18:13:33

**US3312130**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:58:40**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:38:53
User entered 'Amendment 2 (2)'	Christa Estrada (b) (4) (b) (4)	18 Aug 2020 18:13:33

**US3312130**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:58:40**

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:38:53
User entered 'Yes (Y)'	Christa Estrada (b) (4) (b) (4)	18 Aug 2020 18:13:33

**US3312130**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:58:40**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:38:53
User entered empty.	Christa Estrada (b) (4) (b) (4)	18 Aug 2020 18:13:33

**US3312130**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:58:40**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:38:53
User entered empty.	Christa Estrada (b) (4) (b) (4)	18 Aug 2020 18:13:33

**US3312130**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:58:40**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:38:53
User entered 'No (N)'	Christa Estrada (b) (4) (b) (4)	18 Aug 2020 18:13:33

**US3312130**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:58:40**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:38:53
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	18 Aug 2020 16:14:24

**US3312130**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:58:40**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered 'I'	System	18 Aug 2020 18:13:54



**US3312130**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 09 Jun 2021 16:58:40**

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:09:14
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
User entered 'Yes (Y)'	Christa Estrada (b) (4)	18 Aug 2020 18:13:54

**US3312130**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 09 Jun 2021 16:58:40**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:39:05
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:05:27

US3312130

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:58:40

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type II diabetes mellitus - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	21 Aug 2020 19:08:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 19:08:22
Data point term sent to Coder	System	21 Aug 2020 19:07:18
User entered 'Diabetes Mellitus Type II'	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:06:25

**US3312130**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
User entered 'un UNK 2010'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:06:25

**US3312130**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
User entered '0'	(b) (4)	21 Aug 2020 19:06:25
	Karol Moore (b) (4)	
	(b) (4)	

**US3312130**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
User entered 'Yes (Y)'	(b) (4)	
	Karol Moore (b) (4)	21 Aug 2020 19:06:25
	(b) (4)	

**US3312130**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:58:40**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
User entered empty.	(b) (4)	21 Aug 2020 19:06:25
	Karol Moore (b) (4)	
	(b) (4)	

**US3312130**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:06:25



**US3312130**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered 'Jan 2010'	System	21 Aug 2020 19:06:25

**US3312130**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered '2010'	System	21 Aug 2020 19:06:25

**US3312130**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered empty.	System	21 Aug 2020 19:06:25

**US3312130**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered empty.	System	21 Aug 2020 19:06:25

US3312130

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:58:40

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
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.	Coder Import (b) (4)	21 Aug 2020 19:08:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 19:08:22
Data point term sent to Coder	System	21 Aug 2020 19:07:19
User entered 'hypertension'	Karol Moore (b) (4)	21 Aug 2020 19:06:39
	(b) (4)	

**US3312130**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
User entered 'un UNK 2010'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:06:39

**US3312130**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
User entered '0'	(b) (4)	21 Aug 2020 19:06:39
	Karol Moore (b) (4)	
	(b) (4)	

**US3312130**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
User entered 'Yes (Y)'	(b) (4)	21 Aug 2020 19:06:39
	Karol Moore (b) (4)	
	(b) (4)	



**US3312130**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:58:40**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
User entered empty.	(b) (4)	21 Aug 2020 19:06:39
	Karol Moore (b) (4)	
	(b) (4)	

**US3312130**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:06:39

**US3312130**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered 'Jan 2010'	System	21 Aug 2020 19:06:39

**US3312130**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered '2010'	System	21 Aug 2020 19:06:39

**US3312130**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered empty.	System	21 Aug 2020 19:06:39

**US3312130**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered empty.	System	21 Aug 2020 19:06:39

US3312130

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:58:40

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	21 Aug 2020 19:09:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 19:09:24
Data point term sent to Coder	System	21 Aug 2020 19:08:23
User entered 'coronary artery disease'	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:07:25

**US3312130**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
User entered 'un UNK 2017'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:07:25



**US3312130**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
User entered '0'	(b) (4)	
	Karol Moore (b) (4)	21 Aug 2020 19:07:25
	(b) (4)	

**US3312130**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:58:40**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
User entered 'Yes (Y)'	(b) (4)	21 Aug 2020 19:07:25
	Karol Moore (b) (4)	
	(b) (4)	

**US3312130**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:58:40**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
User entered empty.	(b) (4)	21 Aug 2020 19:07:25
	Karol Moore (b) (4)	
	(b) (4)	

**US3312130**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:58:40**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
User entered '0'	(b) (4)	21 Aug 2020 19:07:25
	Karol Moore (b) (4)	
	(b) (4)	

**US3312130**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:58:40**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered 'Jan 2017'	System	21 Aug 2020 19:07:25

**US3312130**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:58:40**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered '2017'	System	21 Aug 2020 19:07:25

**US3312130**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:58:40**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered empty.	System	21 Aug 2020 19:07:25

**US3312130**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:58:40**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered empty.	System	21 Aug 2020 19:07:25



US3312130

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:58:40

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
User coded data point as SOC: Surgical and medical procedures, HLGT: Vascular therapeutic procedures, HLT: Vascular therapeutic procedures NEC, PT: Angioplasty, LLT: Angioplasty - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	21 Aug 2020 19:09:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 19:09:24
Data point term sent to Coder	System	21 Aug 2020 19:08:23
User entered 'angioplasty'	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:07:51

**US3312130**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
User entered '13 Nov 2017'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:07:51

**US3312130**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
User entered '0'	(b) (4)	
	Karol Moore (b) (4)	21 Aug 2020 19:07:51
	(b) (4)	

**US3312130**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:58:40**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
User entered 'No (N)'	(b) (4)	
	Karol Moore (b) (4)	21 Aug 2020 19:07:51
	(b) (4)	

**US3312130**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:58:40**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
User entered '13 Nov 2017'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:07:51

**US3312130**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:58:40**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
User entered '0'	(b) (4)	
	Karol Moore (b) (4)	21 Aug 2020 19:07:51
	(b) (4)	

**US3312130**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:58:40**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered 'Nov 2017'	System	21 Aug 2020 19:07:51

**US3312130**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:58:40**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered '2017'	System	21 Aug 2020 19:07:51



**US3312130**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:58:40**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered 'Nov 2017'	System	21 Aug 2020 19:07:51

**US3312130**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:58:40**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered '2017'	System	21 Aug 2020 19:07:51

US3312130

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:58:40

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
User coded data point as SOC: Injury, poisoning and procedural complications, HLT: Injuries NEC, HLT: Muscle, tendon and ligament injuries, PT: Tendon rupture, LLT: Biceps tendon rupture - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 05:17:24
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 05:17:24
Data point term sent to Coder	System	21 Aug 2020 19:09:24
User entered 'right bicep tendon tear'	Karol Moore (b) (4)	21 Aug 2020 19:08:44

**US3312130**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
User entered 'un Dec 2018'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:08:44

**US3312130**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
User entered '0'	(b) (4)	21 Aug 2020 19:08:44
	Karol Moore (b) (4)	
	(b) (4)	

**US3312130**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:58:40**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
User entered 'No (N)'	(b) (4)	
	Karol Moore (b) (4)	21 Aug 2020 19:08:44
	(b) (4)	

**US3312130**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:58:40**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
User entered 'un Dec 2018'	(b) (4)	
	Karol Moore (b) (4)	21 Aug 2020 19:08:44
	(b) (4)	

**US3312130**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:58:40**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
User entered '0'	(b) (4)	
	Karol Moore (b) (4)	21 Aug 2020 19:08:44
	(b) (4)	



**US3312130**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:58:40**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered 'Dec 2018'	System	21 Aug 2020 19:08:44

**US3312130**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:58:40**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered '2018'	System	21 Aug 2020 19:08:44

**US3312130**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:58:40**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered 'Dec 2018'	System	21 Aug 2020 19:08:44

**US3312130**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:58:40**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered '2018'	System	21 Aug 2020 19:08:44

US3312130

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:58:40

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related disorders NEC, PT: Rotator cuff syndrome, LLT: Rotator cuff tear - 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)	21 Aug 2020 19:10:25
Data point term sent to Coder	(b) (4)	
User entered 'right rotator cuff tear'	System	21 Aug 2020 19:09:26
	Karol Moore (b) (4)	21 Aug 2020 19:09:14
	(b) (4)	

**US3312130**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
User entered 'un Dec 2018'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:09:14

**US3312130**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
User entered '0'	(b) (4)	21 Aug 2020 19:09:14
	Karol Moore (b) (4)	
	(b) (4)	

**US3312130**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 16:58:40**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
User entered 'No (N)'	(b) (4)	
	Karol Moore (b) (4)	21 Aug 2020 19:09:14
	(b) (4)	



**US3312130**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 16:58:40**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
User entered 'un Dec 2018'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:09:14

**US3312130**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 16:58:40**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
User entered '0'	(b) (4)	
	Karol Moore (b) (4)	21 Aug 2020 19:09:14
	(b) (4)	

**US3312130**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 16:58:40**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered 'Dec 2018'	System	21 Aug 2020 19:09:14

**US3312130**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 16:58:40**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered '2018'	System	21 Aug 2020 19:09:14

**US3312130**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 16:58:40**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered 'Dec 2018'	System	21 Aug 2020 19:09:14

**US3312130**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 16:58:40**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered '2018'	System	21 Aug 2020 19:09:14

US3312130

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:58:40

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
User coded data point as SOC: Surgical and medical procedures, HLGT: Soft tissue therapeutic procedures, HLT: Tendon therapeutic procedures, PT: Tenoplasty, LLT: Tendon repair - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	22 Aug 2020 05:17:24
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Aug 2020 05:17:24
Data point term sent to Coder	System	21 Aug 2020 19:10:28
User entered 'right bicep tendon repair'	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:09:52

**US3312130**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
User entered 'un Dec 2018'	(b) (4)	
	Karol Moore (b) (4)	21 Aug 2020 19:09:52
	(b) (4)	



**US3312130**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:09:52

**US3312130**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 16:58:40**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
User entered 'No (N)'	(b) (4)	
	Karol Moore (b) (4)	21 Aug 2020 19:09:52
	(b) (4)	

**US3312130**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 16:58:40**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
User entered 'un Dec 2018'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:09:52

**US3312130**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 16:58:40**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:09:52

**US3312130**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 16:58:40**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered 'Dec 2018'	System	21 Aug 2020 19:09:52

**US3312130**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 16:58:40**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered '2018'	System	21 Aug 2020 19:09:52

**US3312130**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 16:58:40**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered 'Dec 2018'	System	21 Aug 2020 19:09:52

**US3312130**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 16:58:40**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered '2018'	System	21 Aug 2020 19:09:52



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Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:58:40

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Rotator cuff repair, LLT: Rotator cuff repair - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	21 Aug 2020 19:11:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 19:11:30
Data point term sent to Coder	System	21 Aug 2020 19:10:29
User entered 'right rotator cuff repair'	Karol Moore (b) (4)	21 Aug 2020 19:10:19
	(b) (4)	

**US3312130**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
User entered 'un Dec 2018'	(b) (4)	
	Karol Moore (b) (4)	21 Aug 2020 19:10:19
	(b) (4)	

**US3312130**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
User entered '0'	(b) (4)	
	Karol Moore (b) (4)	21 Aug 2020 19:10:19
	(b) (4)	

**US3312130**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 16:58:40**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
User entered 'No (N)'	(b) (4)	
	Karol Moore (b) (4)	21 Aug 2020 19:10:19
	(b) (4)	

**US3312130**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 16:58:40**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
User entered 'un Dec 2018'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:10:19

**US3312130**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 16:58:40**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
User entered '0'	(b) (4)	
	Karol Moore (b) (4)	21 Aug 2020 19:10:19
	(b) (4)	

**US3312130**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 16:58:40**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered 'Dec 2018'	System	21 Aug 2020 19:10:19

**US3312130**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 16:58:40**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered '2018'	System	21 Aug 2020 19:10:19



**US3312130**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 16:58:40**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered 'Dec 2018'	System	21 Aug 2020 19:10:19

**US3312130**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 16:58:40**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered '2018'	System	21 Aug 2020 19:10:19

US3312130

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:58:40

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Nasal disorders NEC, PT: Nasal septum deviation, LLT: Deviated nasal septum - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 19:12:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 19:12:17
Data point term sent to Coder	System	21 Aug 2020 19:11:31
User entered 'deviated septum'	Karol Moore (b) (4)	21 Aug 2020 19:10:43
	(b) (4)	

US3312130

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:58:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
User closed query 'Per CDM: "Medical history start date" and 'Date of Informed Consent' are on the same day. please review and update as per CCGs page 22. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Oct 2020 14:31:34
Query 'Per CDM: "Medical history start date" and 'Date of Informed Consent' are on the same day. please review and update as per CCGs page 22. Thank you.' answered with 'Reviewed source and confirmed start date of 1988. End date reconciled.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 17:52:38
User entered 'un UNK 1988' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Oct 2020 17:52:16
User opened query 'Per CDM: "Medical history start date" and 'Date of Informed Consent' are on the same day. please review and update as per CCGs page 22. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 10:06:56
User entered '18 Aug 2020'	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:10:43

**US3312130**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:10:43

**US3312130**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 16:58:40**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
User entered 'Yes (Y)'	(b) (4)	
	Karol Moore (b) (4)	21 Aug 2020 19:10:43
	(b) (4)	

**US3312130**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 16:58:40**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
User entered empty.	(b) (4)	21 Aug 2020 19:10:43
	Karol Moore (b) (4)	
	(b) (4)	

**US3312130**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 16:58:40**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:10:43



**US3312130**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 16:58:40**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered 'Jan 1988'	System	23 Oct 2020 17:52:16
User entered 'Aug 2020'	System	21 Aug 2020 19:10:43

**US3312130**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 16:58:40**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered '1988'	System	23 Oct 2020 17:52:16
User entered '2020'	System	21 Aug 2020 19:10:43

**US3312130**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 16:58:40**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered empty.	System	21 Aug 2020 19:10:43

**US3312130**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 16:58:40**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered empty.	System	21 Aug 2020 19:10:43

US3312130

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:58:40

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF (please enter associated condition in a separate entry). Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 07:47:11
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF (please enter associated condition in a separate entry). Please verify and update as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 20:40:47
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF (please enter associated condition in a separate entry). Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Feb 2021 15:45:00
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:34:47
User coded data point as SOC: Surgical and medical procedures, HLG: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\\23.0.	(b) (4)	17 Feb 2021 12:35:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Feb 2021 12:35:58
Data point term sent to Coder	System	17 Feb 2021 12:35:02
User entered 'cholecystectomy'	(b) (4), (b) (6)	17 Feb 2021 12:34:19

**US3312130**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:34:47
User entered 'un UNK 2000'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:34:19

**US3312130**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:34:47
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:34:19

**US3312130**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 16:58:40**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:34:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:34:19



**US3312130**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 16:58:40**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:34:47
User entered 'un UNK 2000'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:34:19

**US3312130**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 16:58:40**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:34:47
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:34:19

**US3312130**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 16:58:40**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered 'Jan 2000'	System	17 Feb 2021 12:34:19

**US3312130**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 16:58:40**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered '2000'	System	17 Feb 2021 12:34:19

**US3312130**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 16:58:40**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered 'Jan 2000'	System	17 Feb 2021 12:34:19

**US3312130**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 16:58:40**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered '2000'	System	17 Feb 2021 12:34:19

US3312130

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:58:40

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:18:30
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc degeneration, LLT: Lumbar disc degeneration - version MedDRA\\23.0.	Coder Import (b) (4)	07 Apr 2021 21:50:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	07 Apr 2021 21:49:45
Data point term sent to Coder	System	07 Apr 2021 21:49:32
Coding entries removed.	(b) (4), (b) (6)	07 Apr 2021 21:49:32
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 21:49:32
User entered 'DEGENERATIVE DISC DISEASE (Lumbar)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 21:49:32
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:34:47
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc degeneration, LLT: Degenerative disc disease - version MedDRA\\23.0.	Coder Import (b) (4)	17 Feb 2021 12:35:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	17 Feb 2021 12:35:58
Data point term sent to Coder	System	17 Feb 2021 12:35:02
User entered 'degenerative disc disease'	(b) (4), (b) (6)	17 Feb 2021 12:34:42

**US3312130**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:34:47
User entered 'un UNK 2010'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:34:42



**US3312130**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:34:47
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:34:42

**US3312130**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 16:58:40**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:34:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:34:42

**US3312130**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 16:58:40**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:34:47
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:34:42

**US3312130**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 16:58:40**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:34:47
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:34:42

**US3312130**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 16:58:40**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered 'Jan 2010'	System	17 Feb 2021 12:34:42

**US3312130**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 16:58:40**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered '2010'	System	17 Feb 2021 12:34:42

**US3312130**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 16:58:40**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered empty.	System	17 Feb 2021 12:34:42

**US3312130**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 16:58:40**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered empty.	System	17 Feb 2021 12:34:42



US3312130

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:58:40

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:34:47
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Spinal osteoarthritis, LLT: Lumbo-sacral spondylosis - version MedDRA\\23.0.	Coder Import (b) (4)	17 Feb 2021 12:36:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Feb 2021 12:36:58
Data point term sent to Coder	System	17 Feb 2021 12:36:03
User entered 'lumbosacral spondylosis'	(b) (4), (b) (6)	17 Feb 2021 12:35:03

**US3312130**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:34:47
User entered 'un UNK 2010'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:35:03

**US3312130**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:34:47
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:35:03

**US3312130**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 16:58:40**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:34:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:35:03

**US3312130**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 16:58:40**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:34:47
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:35:03

**US3312130**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 16:58:40**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:34:47
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:35:03

**US3312130**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 16:58:40**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered 'Jan 2010'	System	17 Feb 2021 12:35:03

**US3312130**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 16:58:40**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered '2010'	System	17 Feb 2021 12:35:03



**US3312130**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 16:58:40**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered empty.	System	17 Feb 2021 12:35:03

**US3312130**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 16:58:40**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered empty.	System	17 Feb 2021 12:35:03

US3312130

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:58:40

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:34:47
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	17 Feb 2021 12:36:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Feb 2021 12:36:58
Data point term sent to Coder	System	17 Feb 2021 12:36:02
User entered 'hyperlipidemia'	(b) (4), (b) (6)	17 Feb 2021 12:35:19

**US3312130**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:34:47
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:35:19

**US3312130**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:34:47
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:35:19

**US3312130**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 16:58:40**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:34:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:35:19

**US3312130**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 16:58:40**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:34:47
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:35:19

**US3312130**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 16:58:40**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:34:47
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:35:19



**US3312130**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 16:58:40**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered 'Jan 2015'	System	17 Feb 2021 12:35:19

**US3312130**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 16:58:40**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered '2015'	System	17 Feb 2021 12:35:19

**US3312130**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 16:58:40**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered empty.	System	17 Feb 2021 12:35:19

**US3312130**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 16:58:40**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered empty.	System	17 Feb 2021 12:35:19

US3312130

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:58:40

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:34:47
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine headache - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	17 Feb 2021 12:36:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Feb 2021 12:36:59
Data point term sent to Coder	System	17 Feb 2021 12:36:02
User entered 'migraine headaches'	(b) (4), (b) (6)	17 Feb 2021 12:35:36

**US3312130**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:34:47
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:35:36

**US3312130**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:34:47
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:35:36

**US3312130**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 16:58:40**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:34:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:35:36



**US3312130**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 16:58:40**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:34:47
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:35:36

**US3312130**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 16:58:40**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:34:47
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:35:36

**US3312130**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 16:58:40**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered 'Jan 2015'	System	17 Feb 2021 12:35:36

**US3312130**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 16:58:40**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered '2015'	System	17 Feb 2021 12:35:36

**US3312130**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 16:58:40**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered empty.	System	17 Feb 2021 12:35:36

**US3312130**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 16:58:40**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered empty.	System	17 Feb 2021 12:35:36

US3312130

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:58:40

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:34:47
User coded data point as SOC: Renal and urinary disorders, HLGT: Renal disorders (excl nephropathies), HLT: Renal failure and impairment, PT: Chronic kidney disease, LLT: Chronic kidney disease stage 3 - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	17 Feb 2021 12:36:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Feb 2021 12:36:59
Data point term sent to Coder	System	17 Feb 2021 12:36:02
User entered 'chronic kidney disease stage 3'	(b) (4), (b) (6)	17 Feb 2021 12:36:01

**US3312130**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:34:47
User entered 'un UNK 2010'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:36:01



**US3312130**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:34:47
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:36:01

**US3312130**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 16:58:40**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:34:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:36:01

**US3312130**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 16:58:40**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:34:47
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:36:01

**US3312130**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 16:58:40**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:34:47
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:36:01

**US3312130**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 16:58:40**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered 'Jan 2010'	System	17 Feb 2021 12:36:01

**US3312130**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 16:58:40**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered '2010'	System	17 Feb 2021 12:36:01

**US3312130**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 16:58:40**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered empty.	System	17 Feb 2021 12:36:01

**US3312130**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 16:58:40**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered empty.	System	17 Feb 2021 12:36:01



US3312130

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:58:40

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:34:47
User coded data point as SOC: Psychiatric disorders, HLGT: Psychiatric disorders NEC, HLT: Substance related and addictive disorders, PT: Substance abuse, LLT: Polysubstance abuse - version MedDRA\\23.0.	Coder Import (b) (4)	17 Feb 2021 12:38:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Feb 2021 12:38:04
Data point term sent to Coder	System	17 Feb 2021 12:37:04
User entered 'polysubstance abuse'	(b) (4), (b) (6)	17 Feb 2021 12:36:27

**US3312130**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:34:47
User entered 'un UNK 2010'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:36:27

**US3312130**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:34:47
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:36:27

**US3312130**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 16:58:40**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:34:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:36:27

**US3312130**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 16:58:40**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:34:47
User entered 'un UNK 2017'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:36:27

**US3312130**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 16:58:40**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:34:47
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:36:27

**US3312130**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 16:58:40**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered 'Jan 2010'	System	17 Feb 2021 12:36:27

**US3312130**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 16:58:40**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered '2010'	System	17 Feb 2021 12:36:27



**US3312130**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 16:58:40**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered 'Jan 2017'	System	17 Feb 2021 12:36:27

**US3312130**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 16:58:40**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered '2017'	System	17 Feb 2021 12:36:27

US3312130

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:58:40

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:34:47
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	17 Feb 2021 12:38:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Feb 2021 12:38:03
Data point term sent to Coder	System	17 Feb 2021 12:37:04
User entered 'anxiety'	(b) (4), (b) (6)	17 Feb 2021 12:36:42

**US3312130**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:34:47
User entered 'un UNK 2005'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:36:42

**US3312130**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:34:47
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:36:42

**US3312130**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 16:58:40**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:34:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:36:42

**US3312130**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 16:58:40**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:34:47
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:36:42

**US3312130**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 16:58:40**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:34:47
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:36:42



**US3312130**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 16:58:40**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered 'Jan 2005'	System	17 Feb 2021 12:36:42

**US3312130**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 16:58:40**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered '2005'	System	17 Feb 2021 12:36:42

**US3312130**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 16:58:40**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered empty.	System	17 Feb 2021 12:36:42

**US3312130**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 16:58:40**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered empty.	System	17 Feb 2021 12:36:42

US3312130

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:58:40

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Angina unstable, LLT: Unstable angina - version MedDRA\\23.0.	Coder Import (b) (4)	10 Mar 2021 23:53:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Mar 2021 23:53:40
Data point term sent to Coder	System	10 Mar 2021 23:53:20
Coding entries removed.	Karol Moore (b) (4)	10 Mar 2021 23:53:19
Signature has been broken.	(b) (4)	
	Karol Moore (b) (4)	10 Mar 2021 23:53:19
User entered 'unstable ANGINA' reason for change:	(b) (4)	
Data Entry Error	Karol Moore (b) (4)	10 Mar 2021 23:53:19
User signature succeeded.	(b) (4)	
	Carlos Fierro (b) (4)	23 Feb 2021 20:34:47
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Angina pectoris, LLT: Angina pectoris - version MedDRA\\23.0.	Coder Import (b) (4)	17 Feb 2021 12:38:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Feb 2021 12:38:03
Data point term sent to Coder	System	17 Feb 2021 12:37:04
User entered 'angina'	(b) (4), (b) (6)	17 Feb 2021 12:37:01

**US3312130**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:34:47
User entered 'un UNK 2017'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:37:01

**US3312130**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:34:47
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:37:01

**US3312130**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 16:58:40**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:34:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:37:01



US3312130

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:58:40

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Signature has been broken.	Karol Moore (b) (4)	10 Mar 2021 23:53:19
User entered 'UN Apr 2018' reason for change: Data Entry Error	Karol Moore (b) (4)	10 Mar 2021 23:53:19
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:34:47
User entered 'un UNK 2017'	(b) (4), (b) (6)	17 Feb 2021 12:37:01

**US3312130**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 16:58:40**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	23 Feb 2021 20:34:47
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:37:01

**US3312130**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 16:58:40**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered 'Jan 2017'	System	17 Feb 2021 12:37:01

**US3312130**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 16:58:40**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered '2017'	System	17 Feb 2021 12:37:01

**US3312130**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 16:58:40**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered 'Apr 2018'	System	10 Mar 2021 23:53:19
User entered 'Jan 2017'	System	17 Feb 2021 12:37:01

**US3312130**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 16:58:40**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered '2018'	System	10 Mar 2021 23:53:19
User entered '2017'	System	17 Feb 2021 12:37:01

US3312130

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:58:40

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholelithiasis, LLT: Cholelithiasis - 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)	17 Mar 2021 20:17:49
Data point term sent to Coder	(b) (4)	
User entered 'cholelithiasis'	Coder Import (b) (4)	17 Mar 2021 20:17:49
	(b) (4)	
	System	17 Mar 2021 20:17:17
	(b) (4), (b) (6)	17 Mar 2021 20:17:08

**US3312130**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'un UNK 2000'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 20:17:08



**US3312130**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 20:17:08

**US3312130**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 16:58:40**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 20:17:08

**US3312130**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 16:58:40**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'un UNK 2000'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 20:17:08

**US3312130**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 16:58:40**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 20:17:08

**US3312130**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 16:58:40**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered 'Jan 2000'	System	17 Mar 2021 20:17:08

**US3312130**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 16:58:40**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered '2000'	System	17 Mar 2021 20:17:08

**US3312130**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 16:58:40**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered 'Jan 2000'	System	17 Mar 2021 20:17:08

**US3312130**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 16:58:40**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered '2000'	System	17 Mar 2021 20:17:08



US3312130

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:58:40

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User coded data point as SOC: Surgical and medical procedures, HLT: Arterial therapeutic procedures (excl aortic), PT: Coronary arterial stent insertion, LLT: Coronary arterial stent insertion - version MedDRA\\23.0.	Coder Import (b) (4)	30 Mar 2021 14:18:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	30 Mar 2021 14:18:40
Data point term sent to Coder	System	25 Mar 2021 19:49:46
User entered 'stent X2 LAD'	(b) (4), (b) (6)	25 Mar 2021 19:48:54

**US3312130**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'un UNK 2017'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 19:48:54

**US3312130**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 19:48:54

US3312130

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:58:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	25 Mar 2021 19:49:00
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Mar 2021 19:49:00
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Mar 2021 19:49:00
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Mar 2021 19:48:54
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 19:48:54

**US3312130**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 09 Jun 2021 16:58:40**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'un UNK 2017'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 19:48:54

**US3312130**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 09 Jun 2021 16:58:40**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:15:19
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 19:48:54

**US3312130**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 09 Jun 2021 16:58:40**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered 'Jan 2017'	System	25 Mar 2021 19:48:54

**US3312130**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 09 Jun 2021 16:58:40**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered '2017'	System	25 Mar 2021 19:48:54



**US3312130**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 09 Jun 2021 16:58:40**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered 'Jan 2017'	System	25 Mar 2021 19:48:54

**US3312130**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 09 Jun 2021 16:58:40**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered '2017'	System	25 Mar 2021 19:48:54

**US3312130**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
User entered 'Yes (Y)'	(b) (4)	
	Karol Moore (b) (4)	21 Aug 2020 19:11:39
	(b) (4)	

**US3312130**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
User entered '18 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:11:39

**US3312130**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
User entered '11:30'	(b) (4)	
	Karol Moore (b) (4)	21 Aug 2020 19:11:39
	(b) (4)	

**US3312130**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered '18 Aug 2020 11:30'	System	21 Aug 2020 19:11:39

**US3312130**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
User entered '69' in	(b) (4) Karol Moore (b) (4)	21 Aug 2020 19:11:39
DataPoint set to visible.	(b) (4) System	18 Aug 2020 18:13:54

US3312130

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:40

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
User entered '213' lb	(b) (4) Karol Moore (b) (4)	21 Aug 2020 19:11:39
DataPoint set to visible.	(b) (4) System	18 Aug 2020 18:13:54



**US3312130**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
Amendment Manager: User entered '31.52037'	System	17 Sep 2020 00:12:08
User entered '31.5'	System	21 Aug 2020 19:11:39
DataPoint set to visible.	System	18 Aug 2020 18:13:54

**US3312130**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered 'kg/m2'	System	21 Aug 2020 19:11:39
DataPoint set to visible.	System	18 Aug 2020 18:13:54

US3312130

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:40

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
User entered missing code ND - Not Done.	(b) (4)	
	Karol Moore (b) (4)	21 Aug 2020 19:11:39
	(b) (4)	

**US3312130**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:11:39

**US3312130**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
User entered empty.	(b) (4)	21 Aug 2020 19:11:39
	Karol Moore (b) (4)	
	(b) (4)	

**US3312130**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:11:39

**US3312130**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered 'bpm'	System	21 Aug 2020 19:11:39

**US3312130**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:11:39



**US3312130**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered 'breaths/min'	System	21 Aug 2020 19:11:39

**US3312130**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:11:39

US3312130

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered 'mmHg'	System	21 Aug 2020 19:11:39

**US3312130**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:11:39

**US3312130**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered 'mmHg'	System	21 Aug 2020 19:11:39

**US3312130**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57

**US3312130**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57

**US3312130**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 16:58:40**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:17:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
User entered 'Yes (Y)'	(b) (4)	21 Aug 2020 19:11:55
	Karol Moore (b) (4)	
	(b) (4)	



**US3312130**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 16:58:40**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:17:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
User entered '18 Aug 2020'	(b) (4)	
	Karol Moore (b) (4)	21 Aug 2020 19:11:55
	(b) (4)	

US3312130

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:58:40

**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 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:39:33
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:13:26

US3312130

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:58:40

**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 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:39:33
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:13:26

US3312130

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:58:40

**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 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:39:33
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:13:26

US3312130

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:58:40

**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 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:39:33
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:13:26

US3312130

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:58:40

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 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:39:33
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:13:26

US3312130

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:58:40

[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 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:39:33
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:13:26

US3312130

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:58:40

**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 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:39:33
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:13:26



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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:58:40

**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 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:39:33
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:13:26

US3312130

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:58:40

[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 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:39:33
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:13:26

US3312130

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:58:40

**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 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:39:33
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:13:26

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:58:40

**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 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:39:33
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:13:26

**US3312130**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 09 Jun 2021 16:58:40**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:39:33
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:13:26

US3312130

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:58:40

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:39:33
User entered empty.	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:13:26

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:58:40

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:13:26

**US3312130**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 09 Jun 2021 16:58:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:39:33
User entered '0'	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:13:26



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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:58:40

**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 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:39:33
User entered '0'	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:13:26

US3312130

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:58:40

**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 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:39:33
User entered '0'	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:13:26

US3312130

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:58:40

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 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:39:33
User entered '0'	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:13:26

**US3312130**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 09 Jun 2021 16:58:40**

**Resides in a single family home** (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:39:33
User entered '0'	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:13:26

**US3312130**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 09 Jun 2021 16:58:40**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
User entered 'I'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:13:26

US3312130

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:58:40

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:39:33
User entered 'resides in community with ongoing person to person transmission'	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:13:26

**US3312130**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:40**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:41:48
User entered 'Yes (Y)'	Christa Estrada (b) (4) (b) (4)	18 Aug 2020 18:14:05

**US3312130**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:40**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:41:48
User entered '18 Aug 2020'	Christa Estrada (b) (4) (b) (4)	18 Aug 2020 18:14:05



**US3312130**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:40**

[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 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:41:48
User entered 'Clinic (Clinic)'	Christa Estrada (b) (4) (b) (4)	18 Aug 2020 18:14:05

**US3312130**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:40**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered 'VISIT1'	System	18 Aug 2020 18:14:05

US3312130

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:58:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:41:59
User entered '18 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	18 Aug 2020 17:39:23

US3312130

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:58:40

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:41:59
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 05:18:46
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:18:46
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	18 Aug 2020 17:39:23
User entered '143852' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	18 Aug 2020 17:39:23

US3312130

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:58:40

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:41:59
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	18 Aug 2020 17:39:23

US3312130

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:58:40

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)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:41:59
User entered 'No (N)'	Christa Estrada (b) (4) (b) (4)	18 Aug 2020 18:14:25

US3312130

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:58:40

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)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:41:59
User entered 'Yes (Y)'	Christa Estrada (b) (4) (b) (4)	18 Aug 2020 18:14:25

**US3312130**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 16:58:40**

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:41:59
User entered 'No (N)'	Christa Estrada (b) (4) (b) (4)	18 Aug 2020 18:14:25



**US3312130**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 16:58:40**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:41:59
User entered 'Yes (Y)'	Christa Estrada (b) (4) (b) (4)	18 Aug 2020 18:14:25

**US3312130**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 16:58:40**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:41:59
User entered 'No (N)'	Christa Estrada (b) (4) (b) (4)	18 Aug 2020 18:14:25

**US3312130**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 16:58:40**

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:00:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 17:51:25
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:34:46
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:18:09

US3312130

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:58:40

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:42:08
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:15:09

**US3312130**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 16:58:40**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:42:08
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:15:09

US3312130

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:58:40

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:42:08
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:15:09

US3312130

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:58:40

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:42:08
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:15:09

US3312130

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:40

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User accepted default value 'Pre-Dose (PREDOSE)'	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:15:09



US3312130

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:42:08
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:15:09

US3312130

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:42:08
User entered '18 Aug 2020'	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:15:09

US3312130

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:42:08
User entered '11:30'	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:15:09

**US3312130**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered '18 Aug 2020 11:30'	System	21 Aug 2020 19:15:09

US3312130

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:40

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:42:08
User entered '98.4' F	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:15:09

US3312130

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:40

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:42:08
User entered 'Oral (Oral)'	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:15:09

**US3312130**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:58:40**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:42:08
User entered empty.	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:15:09

**US3312130**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:42:08
User entered '72'	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:15:09



**US3312130**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered 'bpm'	System	21 Aug 2020 19:15:09

US3312130

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:40

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:42:08
User entered '16'	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:15:09

US3312130

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered 'breaths/min'	System	21 Aug 2020 19:15:09

US3312130

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:40

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:42:08
User entered '142'	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:15:09

US3312130

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered 'mmHg'	System	21 Aug 2020 19:15:09

US3312130

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:42:08
User closed query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	31 Aug 2020 18:51:52
Query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'CORRECT AS ENTERED. NCS. SEE UNSCHEDULED REPEAT VITALS' (Site from System).	Karol Moore (b) (4) (b) (4)	27 Aug 2020 20:40:05
User opened query 'Diastolic Blood Pressure reported System is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		21 Aug 2020 19:15:09
User entered '109'	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:15:09

US3312130

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:40

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered 'mmHg'	System	21 Aug 2020 19:15:09

**US3312130**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 16:58:40**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:42:08
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:15:09



US3312130

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:58:40

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:42:08
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:15:09

US3312130

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:40

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User accepted default value 'Post-Dose (POSTDOSE)'	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:15:09

**US3312130**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:42:08
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:15:09

US3312130

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:42:08
User entered '18 Aug 2020'	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:15:09

US3312130

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:42:08
User entered '13:36'	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:15:09

**US3312130**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered '18 Aug 2020 13:36'	System	21 Aug 2020 19:15:09

US3312130

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:40

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:42:08
User entered '98' F	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:15:09

US3312130

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:40

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:42:08
User entered 'Oral (Oral)'	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:15:09



US3312130

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:40

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:42:08
User entered empty.	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:15:09

US3312130

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:42:08
User entered '67'	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:15:09

**US3312130**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered 'bpm'	System	21 Aug 2020 19:15:09

US3312130

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:40

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:42:08
User entered '16'	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:15:09

**US3312130**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered 'breaths/min'	System	21 Aug 2020 19:15:09

US3312130

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:40

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:18:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Un-verified.	(b) (4) Monica Atwood (b) (4)	03 Feb 2021 17:34:41
User entered '155' reason for change: Data Entry Error	(b) (4) Monica Atwood (b) (4)	03 Feb 2021 17:34:41
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 17:42:08
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	31 Aug 2020 18:52:07
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'CORRECT AS ENTERED. NCS. SEE UNSCHEDULED REPEAT VITALS' (Site from System).	Karol Moore (b) (4) (b) (4)	27 Aug 2020 20:40:14
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	21 Aug 2020 19:15:09
User entered '159'	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:15:09

US3312130

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered 'mmHg'	System	21 Aug 2020 19:15:09

US3312130

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:18:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Un-verified.	(b) (4) Monica Atwood (b) (4)	03 Feb 2021 17:34:41
User entered '102' reason for change: Data Entry Error	(b) (4) Monica Atwood (b) (4)	03 Feb 2021 17:34:41
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 17:42:08
User closed query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	31 Aug 2020 18:52:09
Query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'CORRECT AS ENTERED. NCS. SEE UNSCHEDULED REPEAT VITALS' (Site from System).	Karol Moore (b) (4) (b) (4)	27 Aug 2020 20:40:16
User opened query 'Diastolic Blood Pressure reported System is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		21 Aug 2020 19:15:09
User entered '101'	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:15:09



US3312130

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:40

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered 'mmHg'	System	21 Aug 2020 19:15:09

US3312130

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:58:40

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:42:20
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:15:49

US3312130

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:58:40

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:42:20
User entered empty.	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:15:49

US3312130

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:58:40

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:42:41
User entered 'Yes (Y)'	Christa Estrada (b) (4) (b) (4)	18 Aug 2020 18:14:59

US3312130

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:58:40

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:42:41
User entered empty.	Christa Estrada (b) (4) (b) (4)	18 Aug 2020 18:14:59

US3312130

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:58:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:42:41
User entered empty.	Christa Estrada (b) (4) (b) (4)	18 Aug 2020 18:14:59

US3312130

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:58:40

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered 'MRNA-1273 OR PLACEBO'	System	18 Aug 2020 18:14:59

US3312130

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:58:40

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:42:41
User entered '18 Aug 2020'	Christa Estrada (b) (4) (b) (4)	18 Aug 2020 18:14:59



US3312130

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:58:40

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:42:41
User entered '13:05'	Christa Estrada (b) (4) (b) (4)	18 Aug 2020 18:14:59

**US3312130**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 16:58:40**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered '18 Aug 2020 13:05'	System	18 Aug 2020 18:14:59

US3312130

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:58:40

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:42:41
User entered 'Right Arm (RIGHT ARM)'	Christa Estrada (b) (4) (b) (4)	18 Aug 2020 18:14:59

US3312130

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:58:40

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 17:42:41
User entered 'ONCE'	System	18 Aug 2020 18:14:59

US3312130

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:58:40

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered 'INTRAMUSCULAR'	System	18 Aug 2020 18:14:59

US3312130

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:58:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:42:58
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:16:43

US3312130

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:58:40

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:42:58
User entered '18 Aug 2020'	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:16:43

**US3312130**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:58:40**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:42:58
User entered '12:23'	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:16:43



**US3312130**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:58:40**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered '18 Aug 2020 12:23'	System	21 Aug 2020 19:16:43

US3312130

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:58:40

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:43:08
User entered '18 Aug 2020'	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:16:59

US3312130

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:58:40

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:16:59

US3312130

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:58:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:43:08
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:16:59

**US3312130**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:43:08
User entered '11:58'	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:16:59

**US3312130**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered '18 Aug 2020 11:58'	System	21 Aug 2020 19:16:59

US3312130

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:58:40

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:16:59

US3312130

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:58:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:43:08
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:16:59



**US3312130**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:43:08
User entered empty.	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:16:59

**US3312130**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered empty.	System	21 Aug 2020 19:16:59

**US3312130**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:58:40**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:43:20
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:17:05

**US3312130**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:58:40**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered 'I'	System	21 Aug 2020 19:17:05

US3312130

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
Data entry locked.	System	18 Aug 2020 18:14:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Aug 2020 18:14:59

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 16:58:40**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-18T13:40:02', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '1e1e840f-6224-42a6-b85e-4d5cda337af4' User entered 'Yes (Y)'	System	18 Aug 2020 18:40:19
	System	18 Aug 2020 18:40:19

US3312130

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:58:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-18T13:40:08', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '1e1e840f-6224-42a6-b85e-4d5cda337af4' User entered '98.0'	System	18 Aug 2020 18:40:19
	System	18 Aug 2020 18:40:19

US3312130

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:58:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-18T13:40:14', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '1e1e840f-6224-42a6-b85e-4d5cda337af4'	System	18 Aug 2020 18:40:19
User entered 'No (N)'	System	18 Aug 2020 18:40:19



**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-18T13:40:17', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '1e1e840f-6224-42a6-b85e-4d5cda337af4' User entered '18 Aug 2020 13:40'	System	18 Aug 2020 18:40:19
	System	18 Aug 2020 18:40:19

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
User entered '18 Aug 2020 13:25'	System	18 Aug 2020 18:14:59

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
User entered '18 Aug 2020 15:55'	System	18 Aug 2020 18:14:59

US3312130

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
Data entry locked.	System	18 Aug 2020 18:14:59
User entered 'Day 1, after vaccination (at home)'	System	18 Aug 2020 18:14:59

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 16:58:40**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-18T20:59:32', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '1e509c63-639f-43c2-8dec-16f41bdf7505'	System	19 Aug 2020 17:00:49
User entered 'Yes (Y)'	System	19 Aug 2020 17:00:49

US3312130

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:58:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-18T20:59:41', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '1e509c63-639f-43c2-8dec-16f41bdf7505'	System	19 Aug 2020 17:00:49
User entered '98.0'	System	19 Aug 2020 17:00:49

US3312130

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:58:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-18T20:59:51', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '1e509c63-639f-43c2-8dec-16f41bdf7505'	System	19 Aug 2020 17:00:49
User entered 'No (N)'	System	19 Aug 2020 17:00:49

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-18T20:59:57', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '1e509c63-639f-43c2-8dec-16f41bdf7505'	System	19 Aug 2020 17:00:49
User entered '18 Aug 2020 20:59'	System	19 Aug 2020 17:00:49



**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
User entered '18 Aug 2020 16:50'	System	18 Aug 2020 18:14:59

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
User entered '19 Aug 2020 11:59'	System	18 Aug 2020 18:14:59

US3312130

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
Data entry locked.	System	18 Aug 2020 18:14:59
User entered 'Day 2'	System	18 Aug 2020 18:14:59

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 16:58:40**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-19T19:22:06', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'cd80a202-3143-479a-b6be-137cdeafb32'	System	20 Aug 2020 00:22:28
User entered 'Yes (Y)'	System	20 Aug 2020 00:22:28

US3312130

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:58:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-19T19:22:17', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'cd80a202-3143-479a-b6be-137cdeeafb32' User entered '96.1'	System	20 Aug 2020 00:22:28
	System	20 Aug 2020 00:22:28

US3312130

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:58:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-19T19:22:22', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'cd80a202-3143-479a-b6be-137cdeeafb32'	System	20 Aug 2020 00:22:28
User entered 'No (N)'	System	20 Aug 2020 00:22:28

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-19T19:22:25', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'cd80a202-3143-479a-b6be-137cdeafb32' User entered '19 Aug 2020 19:22'	System	20 Aug 2020 00:22:28
	System	20 Aug 2020 00:22:28

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
User entered '19 Aug 2020 12:00'	System	18 Aug 2020 18:14:59



**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
User entered '20 Aug 2020 11:59'	System	18 Aug 2020 18:14:59

US3312130

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
Data entry locked.	System	18 Aug 2020 18:14:59
User entered 'Day 3'	System	18 Aug 2020 18:14:59

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 16:58:40**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-20T21:41:54', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '5b48c424-a74d-4014-8684-574a4d3fc2d8' User entered 'Yes (Y)'	System	21 Aug 2020 02:42:12
	System	21 Aug 2020 02:42:12

US3312130

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:58:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-20T21:42:01', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '5b48c424-a74d-4014-8684-574a4d3fc2d8' User entered '98.6'	System	21 Aug 2020 02:42:12
	System	21 Aug 2020 02:42:12

US3312130

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:58:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-20T21:42:04', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '5b48c424-a74d-4014-8684-574a4d3fc2d8'	System	21 Aug 2020 02:42:12
User entered 'No (N)'	System	21 Aug 2020 02:42:12

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-20T21:42:08', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '5b48c424-a74d-4014-8684-574a4d3fc2d8' User entered '20 Aug 2020 21:42'	System	21 Aug 2020 02:42:12
	System	21 Aug 2020 02:42:12

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
User entered '20 Aug 2020 12:00'	System	18 Aug 2020 18:14:59

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
User entered '21 Aug 2020 11:59'	System	18 Aug 2020 18:14:59



US3312130

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
Data entry locked.	System	18 Aug 2020 18:14:59
User entered 'Day 4'	System	18 Aug 2020 18:14:59

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 16:58:40**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-21T21:14:00', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'c2869660-b596-436f-b88f-0a020df7460b' User entered 'Yes (Y)'	System	22 Aug 2020 02:14:31
	System	22 Aug 2020 02:14:31

US3312130

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:58:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-21T21:14:22', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'c2869660-b596-436f-b88f-0a020df7460b' User entered '99.0'	System	22 Aug 2020 02:14:31
	System	22 Aug 2020 02:14:31

US3312130

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:58:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-21T21:14:26', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'c2869660-b596-436f-b88f-0a020df7460b' User entered 'No (N)'	System	22 Aug 2020 02:14:31
	System	22 Aug 2020 02:14:31

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-21T21:14:28', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'c2869660-b596-436f-b88f-0a020df7460b' User entered '21 Aug 2020 21:14'	System	22 Aug 2020 02:14:31
	System	22 Aug 2020 02:14:31

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
User entered '21 Aug 2020 12:00'	System	18 Aug 2020 18:14:59

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
User entered '22 Aug 2020 11:59'	System	18 Aug 2020 18:14:59

US3312130

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
Data entry locked.	System	18 Aug 2020 18:14:59
User entered 'Day 5'	System	18 Aug 2020 18:14:59



**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 16:58:40**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-22T19:25:39', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '4aef4c8b-63bc-48c1-96a6-62ae8a0d9bf3' User entered 'Yes (Y)'	System	23 Aug 2020 00:25:59
	System	23 Aug 2020 00:25:59

US3312130

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:58:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-22T19:25:49', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '4aef4c8b-63bc-48c1-96a6-62ae8a0d9bf3' User entered '98.6'	System	23 Aug 2020 00:25:59
	System	23 Aug 2020 00:25:59

US3312130

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:58:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-22T19:25:53', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '4aef4c8b-63bc-48c1-96a6-62ae8a0d9bf3'	System	23 Aug 2020 00:25:59
User entered 'No (N)'	System	23 Aug 2020 00:25:59

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-22T19:25:57', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '4aef4c8b-63bc-48c1-96a6-62ae8a0d9bf3' User entered '22 Aug 2020 19:25'	System	23 Aug 2020 00:25:59
	System	23 Aug 2020 00:25:59

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
User entered '22 Aug 2020 12:00'	System	18 Aug 2020 18:14:59

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
User entered '23 Aug 2020 11:59'	System	18 Aug 2020 18:14:59

US3312130

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
Data entry locked.	System	18 Aug 2020 18:14:59
User entered 'Day 6'	System	18 Aug 2020 18:14:59

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 16:58:40**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-23T21:34:17', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'bd9fbb7d-415f-496d-bde6-b3ae37e8edb3' User entered 'Yes (Y)'	System	24 Aug 2020 02:35:36
	System	24 Aug 2020 02:35:36



US3312130

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:58:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-23T21:35:23', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'bd9fbb7d-415f-496d-bde6-b3ae37e8edb3' User entered '98.1'	System	24 Aug 2020 02:35:36
	System	24 Aug 2020 02:35:36

US3312130

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:58:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-23T21:35:25', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'bd9fbb7d-415f-496d-bde6-b3ae37e8edb3'	System	24 Aug 2020 02:35:36
User entered 'No (N)'	System	24 Aug 2020 02:35:36

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-23T21:35:32', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'bd9fbb7d-415f-496d-bde6-b3ae37e8edb3' User entered '23 Aug 2020 21:35'	System	24 Aug 2020 02:35:36
	System	24 Aug 2020 02:35:36

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
User entered '23 Aug 2020 12:00'	System	18 Aug 2020 18:14:59

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
User entered '24 Aug 2020 11:59'	System	18 Aug 2020 18:14:59

US3312130

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
Data entry locked.	System	18 Aug 2020 18:14:59
User entered 'Day 7'	System	18 Aug 2020 18:14:59

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 16:58:40**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-24T23:06:10', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '1e47fd41-3c1a-4018-9332-481e98718375'	System	25 Aug 2020 04:06:35
User entered 'Yes (Y)'	System	25 Aug 2020 04:06:35

US3312130

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:58:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-24T23:06:25', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '1e47fd41-3c1a-4018-9332-481e98718375' User entered '97.4'	System	25 Aug 2020 04:06:35
	System	25 Aug 2020 04:06:35



US3312130

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:58:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-24T23:06:29', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '1e47fd41-3c1a-4018-9332-481e98718375'	System	25 Aug 2020 04:06:35
User entered 'No (N)'	System	25 Aug 2020 04:06:35

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-24T23:06:32', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '1e47fd41-3c1a-4018-9332-481e98718375'	System	25 Aug 2020 04:06:35
User entered '24 Aug 2020 23:06'	System	25 Aug 2020 04:06:35

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
User entered '24 Aug 2020 12:00'	System	18 Aug 2020 18:14:59

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
User entered '25 Aug 2020 11:59'	System	18 Aug 2020 18:14:59

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
Data entry locked.	System	18 Aug 2020 18:14:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Aug 2020 18:14:59

US3312130

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:58:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-18T13:40:28', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '07903705-fbbc-4ff0-9dcf-caaf081a81ca'	System	18 Aug 2020 18:40:50
User entered 'None (1)'	System	18 Aug 2020 18:40:50

US3312130

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:58:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-18T13:40:35', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '07903705-fbbc-4ff0-9dcf-caaf081a81ca' User entered 'No (N)'	System	18 Aug 2020 18:40:50
	System	18 Aug 2020 18:40:50

US3312130

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:58:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-18T13:40:39', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '07903705-fbbc-4ff0-9dcf-caaf081a81ca' User entered 'No (N)'	System	18 Aug 2020 18:40:50
	System	18 Aug 2020 18:40:50



US3312130

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:58:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-18T13:40:46', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '07903705-fbbc-4ff0-9dcf-caaf081a81ca' User entered 'None (1)'	System	18 Aug 2020 18:40:50
	System	18 Aug 2020 18:40:50

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-18T13:40:49', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '07903705-fbbc-4ff0-9dcf-caaf081a81ca' User entered '18 Aug 2020 13:40'	System	18 Aug 2020 18:40:50
	System	18 Aug 2020 18:40:50

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
User entered '18 Aug 2020 13:25'	System	18 Aug 2020 18:14:59

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
User entered '18 Aug 2020 15:55'	System	18 Aug 2020 18:14:59

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
Data entry locked.	System	18 Aug 2020 18:14:59
User entered 'Day 1, after vaccination (at home)'	System	18 Aug 2020 18:14:59

US3312130

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:58:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-18T21:00:34', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '0542be2c-0d3c-4705-ba3a-997d43106cac' User entered 'None (1)'	System	19 Aug 2020 17:00:51
	System	19 Aug 2020 17:00:51

US3312130

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:58:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-18T21:00:37', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '0542be2c-0d3c-4705-ba3a-997d43106cac' User entered 'No (N)'	System	19 Aug 2020 17:00:51
	System	19 Aug 2020 17:00:51

US3312130

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:58:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-18T21:00:43', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '0542be2c-0d3c-4705-ba3a-997d43106cac' User entered 'No (N)'	System	19 Aug 2020 17:00:51
	System	19 Aug 2020 17:00:51



US3312130

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:58:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-18T21:00:51', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '0542be2c-0d3c-4705-ba3a-997d43106cac' User entered 'None (1)'	System	19 Aug 2020 17:00:51
	System	19 Aug 2020 17:00:51

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-18T21:00:53', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '0542be2c-0d3c-4705-ba3a-997d43106cac'	System	19 Aug 2020 17:00:51
User entered '18 Aug 2020 21:00'	System	19 Aug 2020 17:00:51

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
User entered '18 Aug 2020 16:50'	System	18 Aug 2020 18:14:59

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
User entered '19 Aug 2020 11:59'	System	18 Aug 2020 18:14:59

US3312130

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
Data entry locked.	System	18 Aug 2020 18:14:59
User entered 'Day 2'	System	18 Aug 2020 18:14:59

US3312130

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:58:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-19T19:22:39', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'a3a4b411-8aa2-45e0-9687-277935822624' User entered 'None (1)'	System	20 Aug 2020 00:22:58
	System	20 Aug 2020 00:22:58

US3312130

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:58:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-19T19:22:43', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'a3a4b411-8aa2-45e0-9687-277935822624'	System	20 Aug 2020 00:22:58
User entered 'No (N)'	System	20 Aug 2020 00:22:58

US3312130

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:58:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-19T19:22:47', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'a3a4b411-8aa2-45e0-9687-277935822624' User entered 'No (N)'	System	20 Aug 2020 00:22:58
	System	20 Aug 2020 00:22:58



US3312130

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:58:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-19T19:22:53', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'a3a4b411-8aa2-45e0-9687-277935822624' User entered 'None (1)'	System	20 Aug 2020 00:22:58
	System	20 Aug 2020 00:22:58

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-19T19:22:55', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'a3a4b411-8aa2-45e0-9687-277935822624' User entered '19 Aug 2020 19:22'	System	20 Aug 2020 00:22:58
	System	20 Aug 2020 00:22:58

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
User entered '19 Aug 2020 12:00'	System	18 Aug 2020 18:14:59

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
User entered '20 Aug 2020 11:59'	System	18 Aug 2020 18:14:59

US3312130

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
Data entry locked.	System	18 Aug 2020 18:14:59
User entered 'Day 3'	System	18 Aug 2020 18:14:59

US3312130

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:58:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-20T21:42:15', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '5431fdce-caa4-4ec8-b5f9-2a93823aa85d' User entered 'None (1)'	System	21 Aug 2020 02:42:30
	System	21 Aug 2020 02:42:30

US3312130

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:58:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-20T21:42:18', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '5431fdce-caa4-4ec8-b5f9-2a93823aa85d'	System	21 Aug 2020 02:42:30
User entered 'No (N)'	System	21 Aug 2020 02:42:30

US3312130

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:58:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-20T21:42:22', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '5431fdce-caa4-4ec8-b5f9-2a93823aa85d' User entered 'No (N)'	System	21 Aug 2020 02:42:30
	System	21 Aug 2020 02:42:30



US3312130

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:58:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-20T21:42:25', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '5431fdce-caa4-4ec8-b5f9-2a93823aa85d' User entered 'None (1)'	System	21 Aug 2020 02:42:30
	System	21 Aug 2020 02:42:30

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-20T21:42:27', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '5431fdce-caa4-4ec8-b5f9-2a93823aa85d' User entered '20 Aug 2020 21:42'	System	21 Aug 2020 02:42:30
	System	21 Aug 2020 02:42:30

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
User entered '20 Aug 2020 12:00'	System	18 Aug 2020 18:14:59

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
User entered '21 Aug 2020 11:59'	System	18 Aug 2020 18:14:59

US3312130

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
Data entry locked.	System	18 Aug 2020 18:14:59
User entered 'Day 4'	System	18 Aug 2020 18:14:59

US3312130

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:58:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-21T21:13:40', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '2ad3a572-15ce-490d-a971-a152c635ef18'	System	22 Aug 2020 02:13:58
User entered 'None (1)'	System	22 Aug 2020 02:13:58

US3312130

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:58:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-21T21:13:44', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '2ad3a572-15ce-490d-a971-a152c635ef18'	System	22 Aug 2020 02:13:58
User entered 'No (N)'	System	22 Aug 2020 02:13:58

US3312130

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:58:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-21T21:13:47', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '2ad3a572-15ce-490d-a971-a152c635ef18'	System	22 Aug 2020 02:13:58
User entered 'No (N)'	System	22 Aug 2020 02:13:58



US3312130

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:58:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-21T21:13:50', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '2ad3a572-15ce-490d-a971-a152c635ef18' User entered 'None (1)'	System	22 Aug 2020 02:13:58
	System	22 Aug 2020 02:13:58

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-21T21:13:53', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '2ad3a572-15ce-490d-a971-a152c635ef18' User entered '21 Aug 2020 21:13'	System	22 Aug 2020 02:13:58
	System	22 Aug 2020 02:13:58

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
User entered '21 Aug 2020 12:00'	System	18 Aug 2020 18:14:59

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
User entered '22 Aug 2020 11:59'	System	18 Aug 2020 18:14:59

US3312130

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
Data entry locked.	System	18 Aug 2020 18:14:59
User entered 'Day 5'	System	18 Aug 2020 18:14:59

US3312130

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:58:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-22T19:26:01', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '58e383b2-4a44-40ed-a018-0b0164e2c76c' User entered 'None (1)'	System	23 Aug 2020 00:27:45
	System	23 Aug 2020 00:27:45

US3312130

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:58:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-22T19:26:44', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '58e383b2-4a44-40ed-a018-0b0164e2c76c' User entered 'No (N)'	System	23 Aug 2020 00:27:45
	System	23 Aug 2020 00:27:45

US3312130

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:58:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-22T19:27:30', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '58e383b2-4a44-40ed-a018-0b0164e2c76c' User entered 'No (N)'	System	23 Aug 2020 00:27:45
	System	23 Aug 2020 00:27:45



US3312130

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:58:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-22T19:27:32', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '58e383b2-4a44-40ed-a018-0b0164e2c76c' User entered 'None (1)'	System	23 Aug 2020 00:27:45
	System	23 Aug 2020 00:27:45

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-22T19:27:42', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '58e383b2-4a44-40ed-a018-0b0164e2c76c' User entered '22 Aug 2020 19:27'	System	23 Aug 2020 00:27:45
	System	23 Aug 2020 00:27:45

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
User entered '22 Aug 2020 12:00'	System	18 Aug 2020 18:14:59

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
User entered '23 Aug 2020 11:59'	System	18 Aug 2020 18:14:59

US3312130

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
Data entry locked.	System	18 Aug 2020 18:14:59
User entered 'Day 6'	System	18 Aug 2020 18:14:59

US3312130

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:58:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-23T21:35:36', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'f6abc30d-7c13-4d9a-aa31-23ed8d07d6c3' User entered 'None (1)'	System	24 Aug 2020 02:36:33
	System	24 Aug 2020 02:36:33

US3312130

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:58:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-23T21:35:39', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'f6abc30d-7c13-4d9a-aa31-23ed8d07d6c3' User entered 'No (N)'	System	24 Aug 2020 02:36:33
	System	24 Aug 2020 02:36:33

US3312130

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:58:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-23T21:35:44', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'f6abc30d-7c13-4d9a-aa31-23ed8d07d6c3' User entered 'No (N)'	System	24 Aug 2020 02:36:33
	System	24 Aug 2020 02:36:33



US3312130

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:58:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-23T21:35:47', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'f6abc30d-7c13-4d9a-aa31-23ed8d07d6c3' User entered 'None (1)'	System	24 Aug 2020 02:36:33
	System	24 Aug 2020 02:36:33

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-23T21:36:31', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'f6abc30d-7c13-4d9a-aa31-23ed8d07d6c3' User entered '23 Aug 2020 21:36'	System	24 Aug 2020 02:36:33
	System	24 Aug 2020 02:36:33

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
User entered '23 Aug 2020 12:00'	System	18 Aug 2020 18:14:59

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
User entered '24 Aug 2020 11:59'	System	18 Aug 2020 18:14:59

US3312130

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
Data entry locked.	System	18 Aug 2020 18:14:59
User entered 'Day 7'	System	18 Aug 2020 18:14:59

US3312130

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:58:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-24T23:06:35', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '28594cfe-0175-494c-9785-6ea0c0b01ca8' User entered 'None (1)'	System	25 Aug 2020 04:06:52
	System	25 Aug 2020 04:06:52

US3312130

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:58:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-24T23:06:40', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '28594cfe-0175-494c-9785-6ea0c0b01ca8' User entered 'No (N)'	System	25 Aug 2020 04:06:52
	System	25 Aug 2020 04:06:52

US3312130

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:58:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-24T23:06:43', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '28594cfe-0175-494c-9785-6ea0c0b01ca8' User entered 'No (N)'	System	25 Aug 2020 04:06:52
	System	25 Aug 2020 04:06:52



US3312130

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:58:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-24T23:06:44', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '28594cfe-0175-494c-9785-6ea0c0b01ca8' User entered 'None (1)'	System	25 Aug 2020 04:06:52
	System	25 Aug 2020 04:06:52

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-24T23:06:47', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '28594cfe-0175-494c-9785-6ea0c0b01ca8' User entered '24 Aug 2020 23:06'	System	25 Aug 2020 04:06:52
	System	25 Aug 2020 04:06:52

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
User entered '24 Aug 2020 12:00'	System	18 Aug 2020 18:14:59

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
User entered '25 Aug 2020 11:59'	System	18 Aug 2020 18:14:59

US3312130

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
Data entry locked.	System	18 Aug 2020 18:14:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Aug 2020 18:14:59

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 16:58:40**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-18T13:40:54', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'c8de6844-5887-4c41-9dd1-6bf7bdc3ee00' User entered 'None (0)'	System	18 Aug 2020 18:41:28
	System	18 Aug 2020 18:41:28

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 16:58:40**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-18T13:40:56', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'c8de6844-5887-4c41-9dd1-6bf7bdc3ee00' User entered 'None (0)'	System	18 Aug 2020 18:41:28
	System	18 Aug 2020 18:41:28

US3312130

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:58:40

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-18T13:40:59', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'c8de6844-5887-4c41-9dd1-6bf7bdc3ee00' User entered 'None (0)'	System	18 Aug 2020 18:41:28
	System	18 Aug 2020 18:41:28



US3312130

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:58:40

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-18T13:41:02', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'c8de6844-5887-4c41-9dd1-6bf7bdc3ee00' User entered 'None (0)'	System	18 Aug 2020 18:41:28
	System	18 Aug 2020 18:41:28

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 16:58:40**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-18T13:41:07', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'c8de6844-5887-4c41-9dd1-6bf7bdc3ee00' User entered 'None (0)'	System	18 Aug 2020 18:41:28
	System	18 Aug 2020 18:41:28

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 16:58:40**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-18T13:41:10', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'c8de6844-5887-4c41-9dd1-6bf7bdc3ee00' User entered 'None (0)'	System	18 Aug 2020 18:41:28
	System	18 Aug 2020 18:41:28

US3312130

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:58:40

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)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-18T13:41:23', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'c8de6844-5887-4c41-9dd1-6bf7bdc3ee00'	System	18 Aug 2020 18:41:28
User entered 'No (N)'	System	18 Aug 2020 18:41:28

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-18T13:41:26', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'c8de6844-5887-4c41-9dd1-6bf7bdc3ee00' User entered '18 Aug 2020 13:41'	System	18 Aug 2020 18:41:28
	System	18 Aug 2020 18:41:28

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
User entered '18 Aug 2020 13:25'	System	18 Aug 2020 18:14:59

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
User entered '18 Aug 2020 15:55'	System	18 Aug 2020 18:14:59

US3312130

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
Data entry locked.	System	18 Aug 2020 18:14:59
User entered 'Day 1, after vaccination (at home)'	System	18 Aug 2020 18:14:59



**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 16:58:40**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-18T21:00:57', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '62d515e5-612a-4179-b9dd-b629d1fb9610' User entered 'None (0)'	System	19 Aug 2020 17:00:51
	System	19 Aug 2020 17:00:51

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 16:58:40**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-18T21:01:00', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '62d515e5-612a-4179-b9dd-b629d1fb9610' User entered 'None (0)'	System	19 Aug 2020 17:00:51
	System	19 Aug 2020 17:00:51

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 16:58:40**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-18T21:01:03', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '62d515e5-612a-4179-b9dd-b629d1fb9610' User entered 'None (0)'	System	19 Aug 2020 17:00:51
	System	19 Aug 2020 17:00:51

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 16:58:40**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-18T21:01:06', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '62d515e5-612a-4179-b9dd-b629d1fb9610' User entered 'None (0)'	System	19 Aug 2020 17:00:51
	System	19 Aug 2020 17:00:51

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 16:58:40**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-18T21:01:09', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '62d515e5-612a-4179-b9dd-b629d1fb9610' User entered 'None (0)'	System	19 Aug 2020 17:00:51
	System	19 Aug 2020 17:00:51

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 16:58:40**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-18T21:01:11', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '62d515e5-612a-4179-b9dd-b629d1fb9610' User entered 'None (0)'	System	19 Aug 2020 17:00:51
	System	19 Aug 2020 17:00:51

US3312130

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:58:40

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)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-18T21:01:19', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '62d515e5-612a-4179-b9dd-b629d1fb9610' User entered 'No (N)'	System	19 Aug 2020 17:00:51
	System	19 Aug 2020 17:00:51

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-18T21:01:22', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '62d515e5-612a-4179-b9dd-b629d1fb9610' User entered '18 Aug 2020 21:01'	System	19 Aug 2020 17:00:51
	System	19 Aug 2020 17:00:51



**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
User entered '18 Aug 2020 16:50'	System	18 Aug 2020 18:14:59

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
User entered '19 Aug 2020 11:59'	System	18 Aug 2020 18:14:59

US3312130

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
Data entry locked.	System	18 Aug 2020 18:14:59
User entered 'Day 2'	System	18 Aug 2020 18:14:59

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 16:58:40**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-19T19:23:02', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '761badff-64fb-43bd-9d34-26c1c8c9b007' User entered 'None (0)'	System	20 Aug 2020 00:23:44
	System	20 Aug 2020 00:23:44

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 16:58:40**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-19T19:23:17', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '761badff-64fb-43bd-9d34-26c1c8c9b007' User entered 'None (0)'	System	20 Aug 2020 00:23:44
	System	20 Aug 2020 00:23:44

US3312130

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:58:40

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-19T19:23:21', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '761badff-64fb-43bd-9d34-26c1c8c9b007' User entered 'None (0)'	System	20 Aug 2020 00:23:44
	System	20 Aug 2020 00:23:44

US3312130

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:58:40

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-19T19:23:24', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '761badff-64fb-43bd-9d34-26c1c8c9b007' User entered 'None (0)'	System	20 Aug 2020 00:23:44
	System	20 Aug 2020 00:23:44

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 16:58:40**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-19T19:23:27', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '761badff-64fb-43bd-9d34-26c1c8c9b007' User entered 'None (0)'	System	20 Aug 2020 00:23:44
	System	20 Aug 2020 00:23:44



**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 16:58:40**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-19T19:23:29', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '761badff-64fb-43bd-9d34-26c1c8c9b007' User entered 'None (0)'	System	20 Aug 2020 00:23:44
	System	20 Aug 2020 00:23:44

US3312130

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:58:40

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)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-19T19:23:36', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '761badff-64fb-43bd-9d34-26c1c8c9b007'	System	20 Aug 2020 00:23:44
User entered 'No (N)'	System	20 Aug 2020 00:23:44

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-19T19:23:38', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '761badff-64fb-43bd-9d34-26c1c8c9b007'	System	20 Aug 2020 00:23:44
User entered '19 Aug 2020 19:23'	System	20 Aug 2020 00:23:44

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
User entered '19 Aug 2020 12:00'	System	18 Aug 2020 18:14:59

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
User entered '20 Aug 2020 11:59'	System	18 Aug 2020 18:14:59

US3312130

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
Data entry locked.	System	18 Aug 2020 18:14:59
User entered 'Day 3'	System	18 Aug 2020 18:14:59

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 16:58:40**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-20T21:42:31', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'ffe03bb4-d369-4015-81b3-5c82ec698868' User entered 'None (0)'	System	21 Aug 2020 02:42:50
	System	21 Aug 2020 02:42:50

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 16:58:40**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-20T21:42:33', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'ffe03bb4-d369-4015-81b3-5c82ec698868' User entered 'None (0)'	System	21 Aug 2020 02:42:50
	System	21 Aug 2020 02:42:50



US3312130

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:58:40

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-20T21:42:36', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'ffe03bb4-d369-4015-81b3-5c82ec698868' User entered 'None (0)'	System	21 Aug 2020 02:42:50
	System	21 Aug 2020 02:42:50

US3312130

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:58:40

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-20T21:42:38', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'ffe03bb4-d369-4015-81b3-5c82ec698868' User entered 'None (0)'	System	21 Aug 2020 02:42:50
	System	21 Aug 2020 02:42:50

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 16:58:40**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-20T21:42:40', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'ffe03bb4-d369-4015-81b3-5c82ec698868' User entered 'None (0)'	System	21 Aug 2020 02:42:50
	System	21 Aug 2020 02:42:50

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 16:58:40**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-20T21:42:42', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'ffe03bb4-d369-4015-81b3-5c82ec698868' User entered 'None (0)'	System	21 Aug 2020 02:42:50
	System	21 Aug 2020 02:42:50

US3312130

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:58:40

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)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-20T21:42:46', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'ffe03bb4-d369-4015-81b3-5c82ec698868' User entered 'No (N)'	System	21 Aug 2020 02:42:50
	System	21 Aug 2020 02:42:50

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-20T21:42:48', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'ffe03bb4-d369-4015-81b3-5c82ec698868' User entered '20 Aug 2020 21:42'	System	21 Aug 2020 02:42:50
	System	21 Aug 2020 02:42:50

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
User entered '20 Aug 2020 12:00'	System	18 Aug 2020 18:14:59

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
User entered '21 Aug 2020 11:59'	System	18 Aug 2020 18:14:59



US3312130

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
Data entry locked.	System	18 Aug 2020 18:14:59
User entered 'Day 4'	System	18 Aug 2020 18:14:59

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 16:58:40**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-21T21:14:32', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '843d1867-0d7e-4e5c-8be0-3e9d68e6f7a6'	System	22 Aug 2020 02:14:48
User entered 'None (0)'	System	22 Aug 2020 02:14:48

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 16:58:40**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-21T21:14:34', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '843d1867-0d7e-4e5c-8be0-3e9d68e6f7a6'	System	22 Aug 2020 02:14:48
User entered 'None (0)'	System	22 Aug 2020 02:14:48

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 16:58:40**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-21T21:14:36', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '843d1867-0d7e-4e5c-8be0-3e9d68e6f7a6'	System	22 Aug 2020 02:14:48
User entered 'None (0)'	System	22 Aug 2020 02:14:48

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 16:58:40**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-21T21:14:37', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '843d1867-0d7e-4e5c-8be0-3e9d68e6f7a6'	System	22 Aug 2020 02:14:48
User entered 'None (0)'	System	22 Aug 2020 02:14:48

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 16:58:40**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-21T21:14:39', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '843d1867-0d7e-4e5c-8be0-3e9d68e6f7a6'	System	22 Aug 2020 02:14:48
User entered 'None (0)'	System	22 Aug 2020 02:14:48

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 16:58:40**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-21T21:14:41', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '843d1867-0d7e-4e5c-8be0-3e9d68e6f7a6'	System	22 Aug 2020 02:14:48
User entered 'None (0)'	System	22 Aug 2020 02:14:48

US3312130

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:58:40

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)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-21T21:14:44', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '843d1867-0d7e-4e5c-8be0-3e9d68e6f7a6'	System	22 Aug 2020 02:14:48
User entered 'No (N)'	System	22 Aug 2020 02:14:48



**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-21T21:14:47', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '843d1867-0d7e-4e5c-8be0-3e9d68e6f7a6'	System	22 Aug 2020 02:14:48
User entered '21 Aug 2020 21:14'	System	22 Aug 2020 02:14:48

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
User entered '21 Aug 2020 12:00'	System	18 Aug 2020 18:14:59

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
User entered '22 Aug 2020 11:59'	System	18 Aug 2020 18:14:59

US3312130

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
Data entry locked.	System	18 Aug 2020 18:14:59
User entered 'Day 5'	System	18 Aug 2020 18:14:59

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 16:58:40**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-22T19:28:31', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '39046935-76c7-4a8a-83f3-ca8a970a2224' User entered 'None (0)'	System	23 Aug 2020 00:28:53
	System	23 Aug 2020 00:28:53

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 16:58:40**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-22T19:28:34', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '39046935-76c7-4a8a-83f3-ca8a970a2224' User entered 'None (0)'	System	23 Aug 2020 00:28:53
	System	23 Aug 2020 00:28:53

US3312130

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:58:40

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-22T19:28:36', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '39046935-76c7-4a8a-83f3-ca8a970a2224' User entered 'None (0)'	System	23 Aug 2020 00:28:53
	System	23 Aug 2020 00:28:53

US3312130

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:58:40

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-22T19:28:39', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '39046935-76c7-4a8a-83f3-ca8a970a2224' User entered 'None (0)'	System	23 Aug 2020 00:28:53
	System	23 Aug 2020 00:28:53



**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 16:58:40**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-22T19:28:41', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '39046935-76c7-4a8a-83f3-ca8a970a2224' User entered 'None (0)'	System	23 Aug 2020 00:28:53
	System	23 Aug 2020 00:28:53

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 16:58:40**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-22T19:28:43', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '39046935-76c7-4a8a-83f3-ca8a970a2224' User entered 'None (0)'	System	23 Aug 2020 00:28:53
	System	23 Aug 2020 00:28:53

US3312130

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:58:40

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)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-22T19:28:50', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '39046935-76c7-4a8a-83f3-ca8a970a2224'	System	23 Aug 2020 00:28:53
User entered 'No (N)'	System	23 Aug 2020 00:28:53

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-22T19:28:52', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '39046935-76c7-4a8a-83f3-ca8a970a2224'	System	23 Aug 2020 00:28:53
User entered '22 Aug 2020 19:28'	System	23 Aug 2020 00:28:53

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
User entered '22 Aug 2020 12:00'	System	18 Aug 2020 18:14:59

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
User entered '23 Aug 2020 11:59'	System	18 Aug 2020 18:14:59

US3312130

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
Data entry locked.	System	18 Aug 2020 18:14:59
User entered 'Day 6'	System	18 Aug 2020 18:14:59

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 16:58:40**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-23T21:36:35', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '6d7be8af-0d88-4aa0-ba25-3f0c4bb3551b' User entered 'None (0)'	System	24 Aug 2020 02:37:31
	System	24 Aug 2020 02:37:31



**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 16:58:40**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-23T21:36:37', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '6d7be8af-0d88-4aa0-ba25-3f0c4bb3551b' User entered 'None (0)'	System	24 Aug 2020 02:37:31
	System	24 Aug 2020 02:37:31

US3312130

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:58:40

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-23T21:36:40', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '6d7be8af-0d88-4aa0-ba25-3f0c4bb3551b' User entered 'None (0)'	System	24 Aug 2020 02:37:31
	System	24 Aug 2020 02:37:31

US3312130

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:58:40

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-23T21:36:44', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '6d7be8af-0d88-4aa0-ba25-3f0c4bb3551b' User entered 'None (0)'	System	24 Aug 2020 02:37:31
	System	24 Aug 2020 02:37:31

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 16:58:40**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-23T21:36:46', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '6d7be8af-0d88-4aa0-ba25-3f0c4bb3551b' User entered 'None (0)'	System	24 Aug 2020 02:37:31
	System	24 Aug 2020 02:37:31

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 16:58:40**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-23T21:36:48', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '6d7be8af-0d88-4aa0-ba25-3f0c4bb3551b' User entered 'None (0)'	System	24 Aug 2020 02:37:31
	System	24 Aug 2020 02:37:31

US3312130

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:58:40

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)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-23T21:37:22', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '6d7be8af-0d88-4aa0-ba25-3f0c4bb3551b' User entered 'No (N)'	System	24 Aug 2020 02:37:31
	System	24 Aug 2020 02:37:31

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-23T21:37:27', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '6d7be8af-0d88-4aa0-ba25-3f0c4bb3551b' User entered '23 Aug 2020 21:37'	System	24 Aug 2020 02:37:31
	System	24 Aug 2020 02:37:31

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
User entered '23 Aug 2020 12:00'	System	18 Aug 2020 18:14:59



**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
User entered '24 Aug 2020 11:59'	System	18 Aug 2020 18:14:59

US3312130

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
Data entry locked.	System	18 Aug 2020 18:14:59
User entered 'Day 7'	System	18 Aug 2020 18:14:59

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 16:58:40**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-24T23:06:50', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '20017aca-a600-442e-b504-6373ba2c1dfc' User entered 'None (0)'	System	25 Aug 2020 04:07:06
	System	25 Aug 2020 04:07:06

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 16:58:40**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-24T23:06:52', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '20017aca-a600-442e-b504-6373ba2c1dfc' User entered 'None (0)'	System	25 Aug 2020 04:07:06
	System	25 Aug 2020 04:07:06

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 16:58:40**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-24T23:06:54', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '20017aca-a600-442e-b504-6373ba2c1dfc' User entered 'None (0)'	System	25 Aug 2020 04:07:06
	System	25 Aug 2020 04:07:06

US3312130

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:58:40

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-24T23:06:55', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '20017aca-a600-442e-b504-6373ba2c1dfc' User entered 'None (0)'	System	25 Aug 2020 04:07:06
	System	25 Aug 2020 04:07:06

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 16:58:40**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-24T23:06:57', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '20017aca-a600-442e-b504-6373ba2c1dfc' User entered 'None (0)'	System	25 Aug 2020 04:07:06
	System	25 Aug 2020 04:07:06

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 16:58:40**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-24T23:06:58', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '20017aca-a600-442e-b504-6373ba2c1dfc' User entered 'None (0)'	System	25 Aug 2020 04:07:06
	System	25 Aug 2020 04:07:06



US3312130

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:58:40

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)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-24T23:07:02', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '20017aca-a600-442e-b504-6373ba2c1dfc' User entered 'No (N)'	System	25 Aug 2020 04:07:06
	System	25 Aug 2020 04:07:06

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-08-24T23:07:04', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '20017aca-a600-442e-b504-6373ba2c1dfc' User entered '24 Aug 2020 23:07'	System	25 Aug 2020 04:07:06
	System	25 Aug 2020 04:07:06

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
User entered '24 Aug 2020 12:00'	System	18 Aug 2020 18:14:59

**US3312130**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:06
User entered '25 Aug 2020 11:59'	System	18 Aug 2020 18:14:59

**US3312130**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:40**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:40:33
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	26 Aug 2020 15:18:23

**US3312130**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:40:33
User entered '25 Aug 2020'	Karol Moore (b) (4) (b) (4)	26 Aug 2020 15:18:23

**US3312130**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:40**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:40:33
User entered 'Contact Made (CONTACT MADE)'	Karol Moore (b) (4) (b) (4)	26 Aug 2020 15:18:23

**US3312130**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:40**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:40:33
User entered empty.	Karol Moore (b) (4) (b) (4)	26 Aug 2020 15:18:23



**US3312130**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:58:40**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:07:59
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
User entered 'Yes (Y)'	(b) (4)	
	Karol Moore (b) (4)	26 Aug 2020 15:18:27
	(b) (4)	

**US3312130**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:58:40**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered 'I'	System	26 Aug 2020 15:18:27

**US3312130**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:40**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:39:46
User entered 'Yes (Y)'	Kelly Moen (b) (4) (b) (4)	01 Sep 2020 23:18:54

**US3312130**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:40**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:39:46
User entered '1 Sep 2020'	Kelly Moen (b) (4) (b) (4)	01 Sep 2020 23:18:54

**US3312130**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:40**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:39:46
User entered 'Contact Made (CONTACT MADE)'	Kelly Moen (b) (4) (b) (4)	01 Sep 2020 23:18:54

**US3312130**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:40**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:39:46
User entered empty.	Kelly Moen (b) (4) (b) (4)	01 Sep 2020 23:18:54

**US3312130**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:58:40**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:39:58
User entered 'Yes (Y)'	Kelly Moen (b) (4) (b) (4)	01 Sep 2020 23:18:58

**US3312130**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:58:40**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered 'I'	System	01 Sep 2020 23:18:58



**US3312130**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:40**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:33:49
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	08 Sep 2020 21:31:49

**US3312130**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:33:49
User entered '8 Sep 2020'	Karol Moore (b) (4) (b) (4)	08 Sep 2020 21:31:49

**US3312130**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:40**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:33:49
User entered 'Contact Made (CONTACT MADE)'	Karol Moore (b) (4) (b) (4)	08 Sep 2020 21:31:49

US3312130

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:58:40

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:33:49
User entered empty.	Karol Moore (b) (4) (b) (4)	08 Sep 2020 21:31:49

**US3312130**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:58:40**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:33:54
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	08 Sep 2020 21:31:54

**US3312130**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:58:40**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:57
User entered 'I'	System	08 Sep 2020 21:31:54

US3312130

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:58:40

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:25:59
User closed query 'Per CDM: Please complete remaining V2 forms. ' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 07:30:21
Query 'Per CDM: Please complete remaining V2 forms. ' answered with 'updated' (Site from DM).	Karol Moore (b) (4)	08 Oct 2020 14:35:31
User opened query 'Per CDM: Please complete remaining V2 forms. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:32:35
User entered 'Yes (Y)'	Christa Estrada (b) (4) (b) (4)	18 Sep 2020 19:13:08

**US3312130**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:40**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:25:59
User entered '18 Sep 2020'	Christa Estrada (b) (4) (b) (4)	18 Sep 2020 19:13:08



US3312130

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:58:40

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:25:59
User entered 'Clinic (Clinic)'	Christa Estrada (b) (4) (b) (4)	18 Sep 2020 19:13:08

**US3312130**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:40**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User entered 'VISIT2'	System	18 Sep 2020 19:13:08

US3312130

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:40

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User accepted default value 'Pre-Dose (PREDOSE)'	Karol Moore (b) (4) (b) (4)	08 Oct 2020 14:34:41

US3312130

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:27:44
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	08 Oct 2020 14:34:41

**US3312130**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:27:44
User entered '18 Sep 2020'	Karol Moore (b) (4) (b) (4)	08 Oct 2020 14:34:41

**US3312130**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:58:40**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:27:44
User entered '13:09'	Karol Moore (b) (4) (b) (4)	08 Oct 2020 14:34:41

**US3312130**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User entered '18 Sep 2020 13:09'	System	08 Oct 2020 14:34:41

US3312130

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:40

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:27:44
User entered '97.9' F	Karol Moore (b) (4) (b) (4)	08 Oct 2020 14:34:41



US3312130

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:40

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:27:44
User entered 'Oral (Oral)'	Karol Moore (b) (4) (b) (4)	08 Oct 2020 14:34:41

**US3312130**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:58:40**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:27:44
User entered empty.	Karol Moore (b) (4) (b) (4)	08 Oct 2020 14:34:41

**US3312130**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:27:44
User entered '64'	Karol Moore (b) (4) (b) (4)	08 Oct 2020 14:34:41

**US3312130**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User entered 'bpm'	System	08 Oct 2020 14:34:41

US3312130

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:40

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:27:44
User entered '14'	Karol Moore (b) (4) (b) (4)	08 Oct 2020 14:34:41

US3312130

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User entered 'breaths/min'	System	08 Oct 2020 14:34:41

US3312130

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:40

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:59:19
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Un-verified.	(b) (4) Monica Atwood (b) (4)	03 Feb 2021 17:29:13
User entered '149' reason for change: Data Entry Error	(b) (4) Monica Atwood (b) (4)	03 Feb 2021 17:29:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:27:44
User entered '169'	Karol Moore (b) (4) (b) (4)	08 Oct 2020 14:34:41

US3312130

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User entered 'mmHg'	System	08 Oct 2020 14:34:41



US3312130

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:59:25
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Un-verified.	(b) (4) Monica Atwood (b) (4)	03 Feb 2021 17:29:13
User entered '100' reason for change: Data Entry Error	(b) (4) Monica Atwood (b) (4)	03 Feb 2021 17:29:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:27:44
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	09 Oct 2020 06:48:05
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Correct as entered. NCS. See unscheduled repeat' (Site from System).	Karol Moore (b) (4) (b) (4)	08 Oct 2020 14:35:11
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		08 Oct 2020 14:34:41
User entered '116'	Karol Moore (b) (4) (b) (4)	08 Oct 2020 14:34:41

**US3312130**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User entered 'mmHg'	System	08 Oct 2020 14:34:41

US3312130

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:40

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User accepted default value 'Post-Dose (POSTDOSE)'	Karol Moore (b) (4) (b) (4)	08 Oct 2020 14:34:41

US3312130

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:27:44
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	08 Oct 2020 14:34:41

**US3312130**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:58:40**

**Date of assessment (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:27:44
User entered '18 Sep 2020'	Karol Moore (b) (4) (b) (4)	08 Oct 2020 14:34:41

**US3312130**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:58:40**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:27:44
User entered '14:39'	Karol Moore (b) (4) (b) (4)	08 Oct 2020 14:34:41

**US3312130**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User entered '18 Sep 2020 14:39'	System	08 Oct 2020 14:34:41

**US3312130**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:27:44
User entered '98.5' F	Karol Moore (b) (4) (b) (4)	08 Oct 2020 14:34:41



**US3312130**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:27:44
User entered 'Oral (Oral)'	Karol Moore (b) (4) (b) (4)	08 Oct 2020 14:34:41

US3312130

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:40

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:27:44
User entered empty.	Karol Moore (b) (4) (b) (4)	08 Oct 2020 14:34:41

**US3312130**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:27:44
User entered '63'	Karol Moore (b) (4) (b) (4)	08 Oct 2020 14:34:41

**US3312130**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User entered 'bpm'	System	08 Oct 2020 14:34:41

US3312130

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:40

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:27:44
User entered '16'	Karol Moore (b) (4) (b) (4)	08 Oct 2020 14:34:41

US3312130

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User entered 'breaths/min'	System	08 Oct 2020 14:34:41

**US3312130**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:27:44
User entered '148'	Karol Moore (b) (4) (b) (4)	08 Oct 2020 14:34:41

**US3312130**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User entered 'mmHg'	System	08 Oct 2020 14:34:41



**US3312130**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:27:44
User entered '96'	Karol Moore (b) (4) (b) (4)	08 Oct 2020 14:34:41

US3312130

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:40

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User entered 'mmHg'	System	08 Oct 2020 14:34:41

US3312130

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:58:40

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:27:54
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	08 Oct 2020 14:37:08

**US3312130**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 16:58:40**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:27:54
User entered '18 Sep 2020'	Karol Moore (b) (4) (b) (4)	08 Oct 2020 14:37:08

**US3312130**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 16:58:40**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:28:35
User entered 'Yes (Y)'	Christa Estrada (b) (4) (b) (4)	18 Sep 2020 19:13:29

**US3312130**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 16:58:40**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:28:35
User entered empty.	Christa Estrada (b) (4) (b) (4)	18 Sep 2020 19:13:29

US3312130

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:58:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:28:35
User entered empty.	Christa Estrada (b) (4) (b) (4)	18 Sep 2020 19:13:29

**US3312130**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 16:58:40**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User entered 'MRNA-1273 OR PLACEBO'	System	18 Sep 2020 19:13:29



**US3312130**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 16:58:40**

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:28:35
User entered '18 Sep 2020'	Christa Estrada (b) (4) (b) (4)	18 Sep 2020 19:13:29

US3312130

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:58:40

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:28:35
User entered '14:08'	Christa Estrada (b) (4) (b) (4)	18 Sep 2020 19:13:29

**US3312130**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 16:58:40**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User entered '18 Sep 2020 14:08'	System	18 Sep 2020 19:13:29

**US3312130**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 16:58:40**

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:28:35
User entered 'Right Arm (RIGHT ARM)'	Christa Estrada (b) (4) (b) (4)	18 Sep 2020 19:13:29

**US3312130**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 16:58:40**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:28:35
User entered 'ONCE'	System	18 Sep 2020 19:13:29

US3312130

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:58:40

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User entered 'INTRAMUSCULAR'	System	18 Sep 2020 19:13:29

US3312130

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:58:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:28:44
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	08 Oct 2020 14:37:36

**US3312130**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:58:40**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:28:44
User entered '18 Sep 2020'	Karol Moore (b) (4) (b) (4)	08 Oct 2020 14:37:36



**US3312130**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:58:40**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:28:44
User entered '13:34'	Karol Moore (b) (4) (b) (4)	08 Oct 2020 14:37:36

**US3312130**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:58:40**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User entered '18 Sep 2020 13:34'	System	08 Oct 2020 14:37:36

**US3312130**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 09 Jun 2021 16:58:40**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:28:57
User entered '18 Sep 2020'	Karol Moore (b) (4) (b) (4)	08 Oct 2020 14:37:47

**US3312130**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Karol Moore (b) (4) (b) (4)	08 Oct 2020 14:37:47

**US3312130**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:28:57
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	08 Oct 2020 14:37:47

**US3312130**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:28:57
User entered '13:29'	Karol Moore (b) (4) (b) (4)	08 Oct 2020 14:37:47

**US3312130**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User entered '18 Sep 2020 13:29'	System	08 Oct 2020 14:37:47

**US3312130**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Karol Moore (b) (4) (b) (4)	08 Oct 2020 14:37:47



**US3312130**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:28:57
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	08 Oct 2020 14:37:47

**US3312130**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:28:57
User entered empty.	Karol Moore (b) (4) (b) (4)	08 Oct 2020 14:37:47

**US3312130**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User entered empty.	System	08 Oct 2020 14:37:47

US3312130

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:58:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:29:05
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	08 Oct 2020 14:37:50

**US3312130**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:58:40**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User entered 'I'	System	08 Oct 2020 14:37:50

US3312130

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
Data entry locked.	System	18 Sep 2020 19:13:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 19:13:29

US3312130

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:58:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-18T14:40:52', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '29608264-649b-4516-8488-a4a103523a85' User entered 'Yes (Y)'	System	18 Sep 2020 19:41:16
	System	18 Sep 2020 19:41:16

US3312130

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:58:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-18T14:41:00', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '29608264-649b-4516-8488-a4a103523a85' User entered '98.5'	System	18 Sep 2020 19:41:16
	System	18 Sep 2020 19:41:16



US3312130

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:58:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-18T14:41:07', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '29608264-649b-4516-8488-a4a103523a85'	System	18 Sep 2020 19:41:16
User entered 'No (N)'	System	18 Sep 2020 19:41:16

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-18T14:41:14', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '29608264-649b-4516-8488-a4a103523a85' User entered '18 Sep 2020 14:41'	System	18 Sep 2020 19:41:16
	System	18 Sep 2020 19:41:16

US3312130

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:58:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
User entered '18 Sep 2020 14:28'	System	18 Sep 2020 19:13:29

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
User entered '18 Sep 2020 16:58'	System	18 Sep 2020 19:13:29

US3312130

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
Data entry locked.	System	18 Sep 2020 19:13:29
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 19:13:29

US3312130

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:58:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-19T03:00:49', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'aec43aaf-2fbf-44f3-8bca-97f71e31575f' User entered 'Yes (Y)'	System	19 Sep 2020 08:01:10
	System	19 Sep 2020 08:01:10

US3312130

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:58:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-19T03:00:58', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'aec43aaf-2fbf-44f3-8bca-97f71e31575f' User entered '97.1'	System	19 Sep 2020 08:01:10
	System	19 Sep 2020 08:01:10

US3312130

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:58:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-19T03:01:02', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'aec43aaf-2fbf-44f3-8bca-97f71e31575f'	System	19 Sep 2020 08:01:10
User entered 'No (N)'	System	19 Sep 2020 08:01:10



**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-19T03:01:06', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'aec43aaf-2fbf-44f3-8bca-97f71e31575f' User entered '19 Sep 2020 03:01'	System	19 Sep 2020 08:01:10
	System	19 Sep 2020 08:01:10

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
User entered '18 Sep 2020 17:53'	System	18 Sep 2020 19:13:29

US3312130

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:58:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 19:13:29

US3312130

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
Data entry locked.	System	18 Sep 2020 19:13:29
User entered 'Day 2'	System	18 Sep 2020 19:13:29

US3312130

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:58:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-19T21:23:03', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'fc45e291-48ef-4579-90f8-037be0e1fb8f' User entered 'Yes (Y)'	System	20 Sep 2020 02:23:40
	System	20 Sep 2020 02:23:40

US3312130

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:58:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-19T21:23:29', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'fc45e291-48ef-4579-90f8-037be0e1fb8f' User entered '98.4'	System	20 Sep 2020 02:23:40
	System	20 Sep 2020 02:23:40

US3312130

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:58:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-19T21:23:35', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'fc45e291-48ef-4579-90f8-037be0e1fb8f' User entered 'No (N)'	System	20 Sep 2020 02:23:40
	System	20 Sep 2020 02:23:40

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-19T21:23:38', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'fc45e291-48ef-4579-90f8-037be0e1fb8f' User entered '19 Sep 2020 21:23'	System	20 Sep 2020 02:23:40
	System	20 Sep 2020 02:23:40



US3312130

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:58:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 19:13:29

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 19:13:29

US3312130

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
Data entry locked.	System	18 Sep 2020 19:13:29
User entered 'Day 3'	System	18 Sep 2020 19:13:29

US3312130

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:58:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-21T09:20:30', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '1a3a04cf-8de6-4e47-bf15-ee19d050aaa2'	System	21 Sep 2020 14:20:46
User entered 'Yes (Y)'	System	21 Sep 2020 14:20:46

US3312130

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:58:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-21T09:20:37', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '1a3a04cf-8de6-4e47-bf15-ee19d050aaa2' User entered '97.3'	System	21 Sep 2020 14:20:46
	System	21 Sep 2020 14:20:46

US3312130

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:58:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-21T09:20:40', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '1a3a04cf-8de6-4e47-bf15-ee19d050aaa2'	System	21 Sep 2020 14:20:46
User entered 'No (N)'	System	21 Sep 2020 14:20:46

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-21T09:20:44', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '1a3a04cf-8de6-4e47-bf15-ee19d050aaa2' User entered '21 Sep 2020 09:20'	System	21 Sep 2020 14:20:46
	System	21 Sep 2020 14:20:46

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 19:13:29



**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 19:13:29

US3312130

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
Data entry locked.	System	18 Sep 2020 19:13:29
User entered 'Day 4'	System	18 Sep 2020 19:13:29

US3312130

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:58:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-21T19:18:51', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '263e1552-b602-48cc-808d-127daf9b43'	System	22 Sep 2020 00:19:15
User entered 'Yes (Y)'	System	22 Sep 2020 00:19:15

US3312130

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:58:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-21T19:18:59', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '263e1552-b602-48cc-808d-127daf9b43' User entered '98.1'	System	22 Sep 2020 00:19:15
	System	22 Sep 2020 00:19:15

US3312130

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:58:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-21T19:19:11', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '263e1552-b602-48cc-808d-127daf9b43'	System	22 Sep 2020 00:19:15
User entered 'No (N)'	System	22 Sep 2020 00:19:15

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-21T19:19:13', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '263e1552-b602-48cc-808d-127daf9b43'	System	22 Sep 2020 00:19:15
User entered '21 Sep 2020 19:19'	System	22 Sep 2020 00:19:15

US3312130

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:58:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 19:13:29

US3312130

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:58:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 19:13:29



US3312130

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
Data entry locked.	System	18 Sep 2020 19:13:29
User entered 'Day 5'	System	18 Sep 2020 19:13:29

US3312130

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:58:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-23T02:28:17', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'fccd7152-b8aa-4b64-8032-08cf359fcbea' User entered 'Yes (Y)'	System	23 Sep 2020 07:28:42
	System	23 Sep 2020 07:28:42

US3312130

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:58:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-23T02:28:32', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'fccd7152-b8aa-4b64-8032-08cf359fcbea' User entered '96.4'	System	23 Sep 2020 07:28:42
	System	23 Sep 2020 07:28:42

US3312130

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:58:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-23T02:28:37', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'fccd7152-b8aa-4b64-8032-08cf359fcbea' User entered 'No (N)'	System	23 Sep 2020 07:28:42
	System	23 Sep 2020 07:28:42

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-23T02:28:40', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'fccd7152-b8aa-4b64-8032-08cf359fcbea' User entered '23 Sep 2020 02:28'	System	23 Sep 2020 07:28:42
	System	23 Sep 2020 07:28:42

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 19:13:29

US3312130

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:58:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 19:13:29

US3312130

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
Data entry locked.	System	18 Sep 2020 19:13:29
User entered 'Day 6'	System	18 Sep 2020 19:13:29



US3312130

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:58:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-23T18:28:42', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '304ad9e4-2ee9-4a9a-b53c-005c4990067b' User entered 'Yes (Y)'	System	23 Sep 2020 23:28:58
	System	23 Sep 2020 23:28:58

US3312130

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:58:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-23T18:28:48', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '304ad9e4-2ee9-4a9a-b53c-005c4990067b' User entered '98.4'	System	23 Sep 2020 23:28:58
	System	23 Sep 2020 23:28:58

US3312130

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:58:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-23T18:28:53', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '304ad9e4-2ee9-4a9a-b53c-005c4990067b' User entered 'No (N)'	System	23 Sep 2020 23:28:58
	System	23 Sep 2020 23:28:58

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-23T18:28:55', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '304ad9e4-2ee9-4a9a-b53c-005c4990067b' User entered '23 Sep 2020 18:28'	System	23 Sep 2020 23:28:58
	System	23 Sep 2020 23:28:58

US3312130

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:58:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 19:13:29

US3312130

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:58:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 19:13:29

US3312130

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
Data entry locked.	System	18 Sep 2020 19:13:29
User entered 'Day 7'	System	18 Sep 2020 19:13:29

US3312130

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:58:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-25T08:57:45', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '4831febb-29a0-493a-be8d-5f04502cc3a4' User entered 'Yes (Y)'	System	25 Sep 2020 13:58:23
	System	25 Sep 2020 13:58:23



US3312130

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:58:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-25T08:57:58', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '4831febb-29a0-493a-be8d-5f04502cc3a4' User entered '98.2'	System	25 Sep 2020 13:58:23
	System	25 Sep 2020 13:58:23

US3312130

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:58:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-25T08:58:14', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '4831febb-29a0-493a-be8d-5f04502cc3a4' User entered 'No (N)'	System	25 Sep 2020 13:58:23
	System	25 Sep 2020 13:58:23

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-25T08:58:20', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '4831febb-29a0-493a-be8d-5f04502cc3a4' User entered '25 Sep 2020 08:58'	System	25 Sep 2020 13:58:23
	System	25 Sep 2020 13:58:23

US3312130

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:58:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 19:13:29

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 19:13:29

US3312130

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
Data entry locked.	System	18 Sep 2020 19:13:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 19:13:29

US3312130

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:58:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-18T14:41:30', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '1eb14462-3a73-4351-8fad-9529e11389a5' User entered 'None (1)'	System	18 Sep 2020 19:41:45
	System	18 Sep 2020 19:41:45

US3312130

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:58:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-18T14:41:33', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '1eb14462-3a73-4351-8fad-9529e11389a5' User entered 'No (N)'	System	18 Sep 2020 19:41:45
	System	18 Sep 2020 19:41:45



US3312130

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:58:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-18T14:41:36', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '1eb14462-3a73-4351-8fad-9529e11389a5' User entered 'No (N)'	System	18 Sep 2020 19:41:45
	System	18 Sep 2020 19:41:45

US3312130

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:58:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-18T14:41:40', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '1eb14462-3a73-4351-8fad-9529e11389a5' User entered 'None (1)'	System	18 Sep 2020 19:41:45
	System	18 Sep 2020 19:41:45

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-18T14:41:43', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '1eb14462-3a73-4351-8fad-9529e11389a5' User entered '18 Sep 2020 14:41'	System	18 Sep 2020 19:41:45
	System	18 Sep 2020 19:41:45

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
User entered '18 Sep 2020 14:28'	System	18 Sep 2020 19:13:29

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
User entered '18 Sep 2020 16:58'	System	18 Sep 2020 19:13:29

US3312130

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
Data entry locked.	System	18 Sep 2020 19:13:29
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 19:13:29

US3312130

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:58:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-19T03:01:16', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '31997827-b9e8-46d4-9c2d-b1a8272fac13' User entered 'None (1)'	System	19 Sep 2020 08:01:31
	System	19 Sep 2020 08:01:31

US3312130

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:58:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-19T03:01:19', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '31997827-b9e8-46d4-9c2d-b1a8272fac13' User entered 'No (N)'	System	19 Sep 2020 08:01:31
	System	19 Sep 2020 08:01:31



US3312130

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:58:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-19T03:01:22', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '31997827-b9e8-46d4-9c2d-b1a8272fac13' User entered 'No (N)'	System	19 Sep 2020 08:01:31
	System	19 Sep 2020 08:01:31

US3312130

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:58:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-19T03:01:26', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '31997827-b9e8-46d4-9c2d-b1a8272fac13' User entered 'None (1)'	System	19 Sep 2020 08:01:31
	System	19 Sep 2020 08:01:31

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-19T03:01:29', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '31997827-b9e8-46d4-9c2d-b1a8272fac13' User entered '19 Sep 2020 03:01'	System	19 Sep 2020 08:01:31
	System	19 Sep 2020 08:01:31

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
User entered '18 Sep 2020 17:53'	System	18 Sep 2020 19:13:29

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 19:13:29

US3312130

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
Data entry locked.	System	18 Sep 2020 19:13:29
User entered 'Day 2'	System	18 Sep 2020 19:13:29

US3312130

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:58:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-19T21:23:51', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '479f3884-6886-474d-8da8-d6362da5a528'	System	20 Sep 2020 02:24:35
User entered 'None (1)'	System	20 Sep 2020 02:24:35

US3312130

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:58:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-19T21:23:54', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '479f3884-6886-474d-8da8-d6362da5a528' User entered 'No (N)'	System	20 Sep 2020 02:24:35
	System	20 Sep 2020 02:24:35



US3312130

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:58:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-19T21:24:05', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '479f3884-6886-474d-8da8-d6362da5a528' User entered 'No (N)'	System	20 Sep 2020 02:24:35
	System	20 Sep 2020 02:24:35

US3312130

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:58:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-19T21:24:13', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '479f3884-6886-474d-8da8-d6362da5a528'	System	20 Sep 2020 02:24:35
User entered 'None (1)'	System	20 Sep 2020 02:24:35

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-19T21:24:30', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '479f3884-6886-474d-8da8-d6362da5a528' User entered '19 Sep 2020 21:24'	System	20 Sep 2020 02:24:35
	System	20 Sep 2020 02:24:35

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 19:13:29

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 19:13:29

US3312130

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
Data entry locked.	System	18 Sep 2020 19:13:29
User entered 'Day 3'	System	18 Sep 2020 19:13:29

US3312130

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:58:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-21T09:20:50', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '8466511f-95d1-47cf-904d-b94cbac1dd64' User entered 'None (1)'	System	21 Sep 2020 14:21:08
	System	21 Sep 2020 14:21:08

US3312130

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:58:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-21T09:20:54', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '8466511f-95d1-47cf-904d-b94cbac1dd64' User entered 'No (N)'	System	21 Sep 2020 14:21:08
	System	21 Sep 2020 14:21:08



US3312130

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:58:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-21T09:20:57', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '8466511f-95d1-47cf-904d-b94cbac1dd64' User entered 'No (N)'	System	21 Sep 2020 14:21:08
	System	21 Sep 2020 14:21:08

US3312130

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:58:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-21T09:20:59', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '8466511f-95d1-47cf-904d-b94cbac1dd64' User entered 'None (1)'	System	21 Sep 2020 14:21:08
	System	21 Sep 2020 14:21:08

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-21T09:21:05', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '8466511f-95d1-47cf-904d-b94cbac1dd64' User entered '21 Sep 2020 09:21'	System	21 Sep 2020 14:21:08
	System	21 Sep 2020 14:21:08

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 19:13:29

US3312130

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:58:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 19:13:29

US3312130

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
Data entry locked.	System	18 Sep 2020 19:13:29
User entered 'Day 4'	System	18 Sep 2020 19:13:29

US3312130

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:58:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-21T19:19:17', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'f68ba4c3-2b9d-462a-8750-5b7653c5c982'	System	22 Sep 2020 00:19:40
User entered 'None (1)'	System	22 Sep 2020 00:19:40

US3312130

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:58:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-21T19:19:20', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'f68ba4c3-2b9d-462a-8750-5b7653c5c982'	System	22 Sep 2020 00:19:40
User entered 'No (N)'	System	22 Sep 2020 00:19:40



US3312130

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:58:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-21T19:19:23', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'f68ba4c3-2b9d-462a-8750-5b7653c5c982' User entered 'No (N)'	System	22 Sep 2020 00:19:40
	System	22 Sep 2020 00:19:40

US3312130

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:58:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-21T19:19:27', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'f68ba4c3-2b9d-462a-8750-5b7653c5c982'	System	22 Sep 2020 00:19:40
User entered 'None (1)'	System	22 Sep 2020 00:19:40

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-21T19:19:37', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'f68ba4c3-2b9d-462a-8750-5b7653c5c982'	System	22 Sep 2020 00:19:40
User entered '21 Sep 2020 19:19'	System	22 Sep 2020 00:19:40

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 19:13:29

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 19:13:29

US3312130

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
Data entry locked.	System	18 Sep 2020 19:13:29
User entered 'Day 5'	System	18 Sep 2020 19:13:29

US3312130

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:58:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-23T02:28:47', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'f87568cc-f505-496d-aa20-89a93e61e3a9' User entered 'None (1)'	System	23 Sep 2020 07:29:04
	System	23 Sep 2020 07:29:04

US3312130

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:58:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-23T02:28:51', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'f87568cc-f505-496d-aa20-89a93e61e3a9' User entered 'No (N)'	System	23 Sep 2020 07:29:04
	System	23 Sep 2020 07:29:04



US3312130

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:58:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-23T02:28:54', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'f87568cc-f505-496d-aa20-89a93e61e3a9' User entered 'No (N)'	System	23 Sep 2020 07:29:04
	System	23 Sep 2020 07:29:04

US3312130

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:58:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-23T02:28:57', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'f87568cc-f505-496d-aa20-89a93e61e3a9' User entered 'None (1)'	System	23 Sep 2020 07:29:04
	System	23 Sep 2020 07:29:04

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-23T02:29:03', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'f87568cc-f505-496d-aa20-89a93e61e3a9' User entered '23 Sep 2020 02:29'	System	23 Sep 2020 07:29:04
	System	23 Sep 2020 07:29:04

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 19:13:29

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 19:13:29

US3312130

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
Data entry locked.	System	18 Sep 2020 19:13:29
User entered 'Day 6'	System	18 Sep 2020 19:13:29

US3312130

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:58:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-23T18:28:58', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '62064d26-bf2b-420f-8d78-eb0a90dafa89' User entered 'None (1)'	System	23 Sep 2020 23:29:08
	System	23 Sep 2020 23:29:08

US3312130

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:58:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-23T18:29:00', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '62064d26-bf2b-420f-8d78-eb0a90dafa89' User entered 'No (N)'	System	23 Sep 2020 23:29:08
	System	23 Sep 2020 23:29:08



US3312130

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:58:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-23T18:29:02', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '62064d26-bf2b-420f-8d78-eb0a90dafa89' User entered 'No (N)'	System	23 Sep 2020 23:29:08
	System	23 Sep 2020 23:29:08

US3312130

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:58:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-23T18:29:03', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '62064d26-bf2b-420f-8d78-eb0a90dafa89' User entered 'None (1)'	System	23 Sep 2020 23:29:08
	System	23 Sep 2020 23:29:08

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-23T18:29:05', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '62064d26-bf2b-420f-8d78-eb0a90dafa89' User entered '23 Sep 2020 18:29'	System	23 Sep 2020 23:29:08
	System	23 Sep 2020 23:29:08

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 19:13:29

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 19:13:29

US3312130

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
Data entry locked.	System	18 Sep 2020 19:13:29
User entered 'Day 7'	System	18 Sep 2020 19:13:29

US3312130

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:58:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-25T08:58:26', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'a623df36-b962-4049-940f-b779385f0090' User entered 'None (1)'	System	25 Sep 2020 13:58:42
	System	25 Sep 2020 13:58:42

US3312130

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:58:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-25T08:58:30', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'a623df36-b962-4049-940f-b779385f0090' User entered 'No (N)'	System	25 Sep 2020 13:58:42
	System	25 Sep 2020 13:58:42



US3312130

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:58:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-25T08:58:34', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'a623df36-b962-4049-940f-b779385f0090' User entered 'No (N)'	System	25 Sep 2020 13:58:42
	System	25 Sep 2020 13:58:42

US3312130

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:58:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-25T08:58:36', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'a623df36-b962-4049-940f-b779385f0090' User entered 'None (1)'	System	25 Sep 2020 13:58:42
	System	25 Sep 2020 13:58:42

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-25T08:58:39', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'a623df36-b962-4049-940f-b779385f0090' User entered '25 Sep 2020 08:58'	System	25 Sep 2020 13:58:42
	System	25 Sep 2020 13:58:42

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 19:13:29

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 19:13:29

US3312130

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
Data entry locked.	System	18 Sep 2020 19:13:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 19:13:29

US3312130

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:58:40

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-18T14:41:49', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '852d142e-3a7c-4e2c-8623-1863fa6e933b' User entered 'None (0)'	System	18 Sep 2020 19:42:25
	System	18 Sep 2020 19:42:25

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 16:58:40**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-18T14:41:51', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '852d142e-3a7c-4e2c-8623-1863fa6e933b' User entered 'None (0)'	System	18 Sep 2020 19:42:25
	System	18 Sep 2020 19:42:25



US3312130

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:58:40

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-18T14:42:01', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '852d142e-3a7c-4e2c-8623-1863fa6e933b' User entered 'None (0)'	System	18 Sep 2020 19:42:25
	System	18 Sep 2020 19:42:25

US3312130

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:58:40

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-18T14:42:05', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '852d142e-3a7c-4e2c-8623-1863fa6e933b' User entered 'None (0)'	System	18 Sep 2020 19:42:25
	System	18 Sep 2020 19:42:25

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 16:58:40**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-18T14:42:07', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '852d142e-3a7c-4e2c-8623-1863fa6e933b' User entered 'None (0)'	System	18 Sep 2020 19:42:25
	System	18 Sep 2020 19:42:25

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 16:58:40**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-18T14:42:10', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '852d142e-3a7c-4e2c-8623-1863fa6e933b' User entered 'None (0)'	System	18 Sep 2020 19:42:25
	System	18 Sep 2020 19:42:25

US3312130

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:58:40

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)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-18T14:42:20', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '852d142e-3a7c-4e2c-8623-1863fa6e933b' User entered 'No (N)'	System	18 Sep 2020 19:42:25
	System	18 Sep 2020 19:42:25

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-18T14:42:22', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '852d142e-3a7c-4e2c-8623-1863fa6e933b' User entered '18 Sep 2020 14:42'	System	18 Sep 2020 19:42:25
	System	18 Sep 2020 19:42:25

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
User entered '18 Sep 2020 14:28'	System	18 Sep 2020 19:13:29

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
User entered '18 Sep 2020 16:58'	System	18 Sep 2020 19:13:29



US3312130

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
Data entry locked.	System	18 Sep 2020 19:13:29
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 19:13:29

US3312130

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:58:40

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-19T03:01:33', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '3981472f-12c3-4382-a35b-271baa028e2f' User entered 'None (0)'	System	19 Sep 2020 08:02:00
	System	19 Sep 2020 08:02:00

US3312130

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:58:40

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-19T03:01:37', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '3981472f-12c3-4382-a35b-271baa028e2f' User entered 'None (0)'	System	19 Sep 2020 08:02:00
	System	19 Sep 2020 08:02:00

US3312130

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:58:40

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-19T03:01:40', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '3981472f-12c3-4382-a35b-271baa028e2f' User entered 'None (0)'	System	19 Sep 2020 08:02:00
	System	19 Sep 2020 08:02:00

US3312130

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:58:40

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-19T03:01:42', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '3981472f-12c3-4382-a35b-271baa028e2f' User entered 'None (0)'	System	19 Sep 2020 08:02:00
	System	19 Sep 2020 08:02:00

US3312130

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:58:40

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-19T03:01:44', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '3981472f-12c3-4382-a35b-271baa028e2f' User entered 'None (0)'	System	19 Sep 2020 08:02:00
	System	19 Sep 2020 08:02:00

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 16:58:40**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-19T03:01:46', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '3981472f-12c3-4382-a35b-271baa028e2f' User entered 'None (0)'	System	19 Sep 2020 08:02:00
	System	19 Sep 2020 08:02:00

US3312130

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:58:40

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)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-19T03:01:53', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '3981472f-12c3-4382-a35b-271baa028e2f' User entered 'No (N)'	System	19 Sep 2020 08:02:00
	System	19 Sep 2020 08:02:00



**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-19T03:01:55', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '3981472f-12c3-4382-a35b-271baa028e2f' User entered '19 Sep 2020 03:01'	System	19 Sep 2020 08:02:00
	System	19 Sep 2020 08:02:00

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
User entered '18 Sep 2020 17:53'	System	18 Sep 2020 19:13:29

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 19:13:29

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
Data entry locked.	System	18 Sep 2020 19:13:29
User entered 'Day 2'	System	18 Sep 2020 19:13:29

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 16:58:40**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-19T21:24:36', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '9548d36d-3d99-467b-9160-71ed1cdd0b93' User entered 'None (0)'	System	20 Sep 2020 02:25:03
	System	20 Sep 2020 02:25:03

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 16:58:40**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-19T21:24:38', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '9548d36d-3d99-467b-9160-71ed1cdd0b93' User entered 'None (0)'	System	20 Sep 2020 02:25:03
	System	20 Sep 2020 02:25:03

US3312130

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:58:40

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-19T21:24:43', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '9548d36d-3d99-467b-9160-71ed1cdd0b93' User entered 'None (0)'	System	20 Sep 2020 02:25:03
	System	20 Sep 2020 02:25:03

US3312130

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:58:40

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-19T21:24:44', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '9548d36d-3d99-467b-9160-71ed1cdd0b93' User entered 'None (0)'	System	20 Sep 2020 02:25:03
	System	20 Sep 2020 02:25:03



**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 16:58:40**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-19T21:24:46', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '9548d36d-3d99-467b-9160-71ed1cdd0b93' User entered 'None (0)'	System	20 Sep 2020 02:25:03
	System	20 Sep 2020 02:25:03

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 16:58:40**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-19T21:24:48', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '9548d36d-3d99-467b-9160-71ed1cdd0b93' User entered 'None (0)'	System	20 Sep 2020 02:25:03
	System	20 Sep 2020 02:25:03

US3312130

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:58:40

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)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-19T21:24:54', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '9548d36d-3d99-467b-9160-71ed1cdd0b93' User entered 'No (N)'	System	20 Sep 2020 02:25:03
	System	20 Sep 2020 02:25:03

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-19T21:25:00', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '9548d36d-3d99-467b-9160-71ed1cdd0b93' User entered '19 Sep 2020 21:25'	System	20 Sep 2020 02:25:03
	System	20 Sep 2020 02:25:03

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 19:13:29

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 19:13:29

US3312130

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
Data entry locked.	System	18 Sep 2020 19:13:29
User entered 'Day 3'	System	18 Sep 2020 19:13:29

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 16:58:40**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-21T09:21:11', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'c37e0867-26a2-4677-8d34-ae4424aaaa4e' User entered 'None (0)'	System	21 Sep 2020 14:21:29
	System	21 Sep 2020 14:21:29



**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 16:58:40**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-21T09:21:13', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'c37e0867-26a2-4677-8d34-ae4424aaaa4e' User entered 'None (0)'	System	21 Sep 2020 14:21:29
	System	21 Sep 2020 14:21:29

US3312130

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:58:40

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-21T09:21:15', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'c37e0867-26a2-4677-8d34-ae4424aaaa4e' User entered 'None (0)'	System	21 Sep 2020 14:21:29
	System	21 Sep 2020 14:21:29

US3312130

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:58:40

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-21T09:21:17', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'c37e0867-26a2-4677-8d34-ae4424aaaa4e' User entered 'None (0)'	System	21 Sep 2020 14:21:29
	System	21 Sep 2020 14:21:29

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 16:58:40**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-21T09:21:20', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'c37e0867-26a2-4677-8d34-ae4424aaaa4e' User entered 'None (0)'	System	21 Sep 2020 14:21:29
	System	21 Sep 2020 14:21:29

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 16:58:40**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-21T09:21:22', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'c37e0867-26a2-4677-8d34-ae4424aaaa4e' User entered 'None (0)'	System	21 Sep 2020 14:21:29
	System	21 Sep 2020 14:21:29

US3312130

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:58:40

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)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-21T09:21:25', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'c37e0867-26a2-4677-8d34-ae4424aaaa4e' User entered 'No (N)'	System	21 Sep 2020 14:21:29
	System	21 Sep 2020 14:21:29

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-21T09:21:27', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'c37e0867-26a2-4677-8d34-ae4424aaaa4e' User entered '21 Sep 2020 09:21'	System	21 Sep 2020 14:21:29
	System	21 Sep 2020 14:21:29

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 19:13:29



**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 19:13:29

US3312130

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
Data entry locked.	System	18 Sep 2020 19:13:29
User entered 'Day 4'	System	18 Sep 2020 19:13:29

US3312130

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:58:40

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-21T19:19:40', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '56b91c4d-2ee2-49a4-a777-c73741dc7735' User entered 'None (0)'	System	22 Sep 2020 00:20:00
	System	22 Sep 2020 00:20:00

US3312130

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:58:40

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-21T19:19:42', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '56b91c4d-2ee2-49a4-a777-c73741dc7735' User entered 'None (0)'	System	22 Sep 2020 00:20:00
	System	22 Sep 2020 00:20:00

US3312130

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:58:40

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-21T19:19:43', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '56b91c4d-2ee2-49a4-a777-c73741dc7735' User entered 'None (0)'	System	22 Sep 2020 00:20:00
	System	22 Sep 2020 00:20:00

US3312130

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:58:40

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-21T19:19:44', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '56b91c4d-2ee2-49a4-a777-c73741dc7735' User entered 'None (0)'	System	22 Sep 2020 00:20:00
	System	22 Sep 2020 00:20:00

US3312130

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:58:40

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-21T19:19:46', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '56b91c4d-2ee2-49a4-a777-c73741dc7735' User entered 'None (0)'	System	22 Sep 2020 00:20:00
	System	22 Sep 2020 00:20:00

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 16:58:40**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-21T19:19:48', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '56b91c4d-2ee2-49a4-a777-c73741dc7735' User entered 'None (0)'	System	22 Sep 2020 00:20:00
	System	22 Sep 2020 00:20:00



US3312130

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:58:40

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)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-21T19:19:50', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '56b91c4d-2ee2-49a4-a777-c73741dc7735' User entered 'No (N)'	System	22 Sep 2020 00:20:00
	System	22 Sep 2020 00:20:00

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-21T19:19:52', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '56b91c4d-2ee2-49a4-a777-c73741dc7735' User entered '21 Sep 2020 19:19'	System	22 Sep 2020 00:20:00
	System	22 Sep 2020 00:20:00

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 19:13:29

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 19:13:29

US3312130

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
Data entry locked.	System	18 Sep 2020 19:13:29
User entered 'Day 5'	System	18 Sep 2020 19:13:29

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 16:58:40**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-23T02:29:08', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '8975a7fe-b69d-4b13-a01b-7e021a061c26' User entered 'None (0)'	System	23 Sep 2020 07:29:51
	System	23 Sep 2020 07:29:51

US3312130

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:58:40

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-23T02:29:11', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '8975a7fe-b69d-4b13-a01b-7e021a061c26' User entered 'None (0)'	System	23 Sep 2020 07:29:51
	System	23 Sep 2020 07:29:51

US3312130

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:58:40

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-23T02:29:15', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '8975a7fe-b69d-4b13-a01b-7e021a061c26' User entered 'None (0)'	System	23 Sep 2020 07:29:51
	System	23 Sep 2020 07:29:51



US3312130

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:58:40

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-23T02:29:19', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '8975a7fe-b69d-4b13-a01b-7e021a061c26' User entered 'None (0)'	System	23 Sep 2020 07:29:51
	System	23 Sep 2020 07:29:51

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 16:58:40**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-23T02:29:24', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '8975a7fe-b69d-4b13-a01b-7e021a061c26' User entered 'None (0)'	System	23 Sep 2020 07:29:51
	System	23 Sep 2020 07:29:51

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 16:58:40**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-23T02:29:29', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '8975a7fe-b69d-4b13-a01b-7e021a061c26' User entered 'None (0)'	System	23 Sep 2020 07:29:51
	System	23 Sep 2020 07:29:51

US3312130

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:58:40

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)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-23T02:29:34', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '8975a7fe-b69d-4b13-a01b-7e021a061c26' User entered 'No (N)'	System	23 Sep 2020 07:29:51
	System	23 Sep 2020 07:29:51

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-23T02:29:49', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '8975a7fe-b69d-4b13-a01b-7e021a061c26' User entered '23 Sep 2020 02:29'	System	23 Sep 2020 07:29:51
	System	23 Sep 2020 07:29:51

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 19:13:29

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 19:13:29

US3312130

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:58:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
Data entry locked.	System	18 Sep 2020 19:13:29
User entered 'Day 6'	System	18 Sep 2020 19:13:29



US3312130

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:58:40

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-23T18:29:09', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '4ec9a79f-3ef6-4c64-958e-7fc5c913e562' User entered 'None (0)'	System	23 Sep 2020 23:29:48
	System	23 Sep 2020 23:29:48

US3312130

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:58:40

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-23T18:29:29', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '4ec9a79f-3ef6-4c64-958e-7fc5c913e562'	System	23 Sep 2020 23:29:48
User entered 'No interference with activity (1)'	System	23 Sep 2020 23:29:48

US3312130

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:58:40

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-23T18:29:15', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '4ec9a79f-3ef6-4c64-958e-7fc5c913e562' User entered 'None (0)'	System	23 Sep 2020 23:29:48
	System	23 Sep 2020 23:29:48

US3312130

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:58:40

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-23T18:29:34', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '4ec9a79f-3ef6-4c64-958e-7fc5c913e562'	System	23 Sep 2020 23:29:48
User entered 'No interference with activity (1)'	System	23 Sep 2020 23:29:48

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 16:58:40**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-23T18:29:37', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '4ec9a79f-3ef6-4c64-958e-7fc5c913e562' User entered 'None (0)'	System	23 Sep 2020 23:29:48
	System	23 Sep 2020 23:29:48

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 16:58:40**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-23T18:29:40', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '4ec9a79f-3ef6-4c64-958e-7fc5c913e562' User entered 'None (0)'	System	23 Sep 2020 23:29:48
	System	23 Sep 2020 23:29:48

US3312130

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:58:40

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)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-23T18:29:43', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '4ec9a79f-3ef6-4c64-958e-7fc5c913e562'	System	23 Sep 2020 23:29:48
User entered 'No (N)'	System	23 Sep 2020 23:29:48

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-23T18:29:46', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '4ec9a79f-3ef6-4c64-958e-7fc5c913e562' User entered '23 Sep 2020 18:29'	System	23 Sep 2020 23:29:48
	System	23 Sep 2020 23:29:48



**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 19:13:29

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 19:13:29

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
Data entry locked.	System	18 Sep 2020 19:13:29
User entered 'Day 7'	System	18 Sep 2020 19:13:29

US3312130

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:58:40

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-25T08:58:45', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '7a3784d2-2a1a-499e-a255-7091ad8a8d95' User entered 'None (0)'	System	25 Sep 2020 13:59:09
	System	25 Sep 2020 13:59:09

US3312130

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:58:40

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-25T08:58:47', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '7a3784d2-2a1a-499e-a255-7091ad8a8d95' User entered 'None (0)'	System	25 Sep 2020 13:59:09
	System	25 Sep 2020 13:59:09

US3312130

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:58:40

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-25T08:58:50', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '7a3784d2-2a1a-499e-a255-7091ad8a8d95' User entered 'None (0)'	System	25 Sep 2020 13:59:09
	System	25 Sep 2020 13:59:09

US3312130

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:58:40

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-25T08:58:55', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '7a3784d2-2a1a-499e-a255-7091ad8a8d95' User entered 'None (0)'	System	25 Sep 2020 13:59:09
	System	25 Sep 2020 13:59:09

US3312130

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:58:40

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-25T08:58:57', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '7a3784d2-2a1a-499e-a255-7091ad8a8d95' User entered 'None (0)'	System	25 Sep 2020 13:59:09
	System	25 Sep 2020 13:59:09



US3312130

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:58:40

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-25T08:59:00', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '7a3784d2-2a1a-499e-a255-7091ad8a8d95' User entered 'None (0)'	System	25 Sep 2020 13:59:09
	System	25 Sep 2020 13:59:09

US3312130

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:58:40

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)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-25T08:59:03', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '7a3784d2-2a1a-499e-a255-7091ad8a8d95' User entered 'No (N)'	System	25 Sep 2020 13:59:09
	System	25 Sep 2020 13:59:09

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-09-25T08:59:06', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '7a3784d2-2a1a-499e-a255-7091ad8a8d95' User entered '25 Sep 2020 08:59'	System	25 Sep 2020 13:59:09
	System	25 Sep 2020 13:59:09

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 19:13:29

**US3312130**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 16:58:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:27:44
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 19:13:29

**US3312130**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:40**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:29:37
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	08 Oct 2020 14:40:41

**US3312130**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:29:37
User entered '25 Sep 2020'	Karol Moore (b) (4) (b) (4)	08 Oct 2020 14:40:41

**US3312130**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:40**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:29:37
User entered 'Contact Made (CONTACT MADE)'	Karol Moore (b) (4) (b) (4)	08 Oct 2020 14:40:41



**US3312130**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:40**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:29:37
User entered empty.	Karol Moore (b) (4) (b) (4)	08 Oct 2020 14:40:41

**US3312130**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:58:40**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:29:31
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	08 Oct 2020 14:40:45

**US3312130**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:58:40**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User entered 'I'	System	08 Oct 2020 14:40:45

**US3312130**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:40**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:29:58
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	08 Oct 2020 14:41:04

**US3312130**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:40**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:29:58
User entered '02 Oct 2020'	Karol Moore (b) (4) (b) (4)	08 Oct 2020 14:41:04

**US3312130**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:40**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:29:58
User entered 'Contact Made (CONTACT MADE)'	Karol Moore (b) (4) (b) (4)	08 Oct 2020 14:41:04

**US3312130**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:40**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:29:58
User entered empty.	Karol Moore (b) (4) (b) (4)	08 Oct 2020 14:41:04

**US3312130**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:58:40**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:30:04
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	08 Oct 2020 14:41:06



**US3312130**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:58:40**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User entered 'I'	System	08 Oct 2020 14:41:06

**US3312130**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:40**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:30:35
User entered 'Yes (Y)'	Monica Atwood (b) (4) (b) (4)	09 Oct 2020 20:35:56

**US3312130**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:40**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:30:35
User entered '9 Oct 2020'	Monica Atwood (b) (4) (b) (4)	09 Oct 2020 20:35:56

**US3312130**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:40**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:30:35
User entered 'Contact Made (CONTACT MADE)'	Monica Atwood (b) (4) (b) (4)	09 Oct 2020 20:35:56

**US3312130**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:40**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:30:35
User entered empty.	Monica Atwood (b) (4) (b) (4)	09 Oct 2020 20:35:56

**US3312130**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:58:40**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:30:40
User entered 'Yes (Y)'	Monica Atwood (b) (4) (b) (4)	09 Oct 2020 20:36:01

**US3312130**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:58:40**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User entered 'I'	System	09 Oct 2020 20:36:01

**US3312130**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:40**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:20:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 15:02:11



**US3312130**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:40**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:20:58
User entered '16 Oct 2020'	(b) (4), (b) (6)	19 Oct 2020 15:02:11

**US3312130**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:40**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:20:58
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	19 Oct 2020 15:02:11

**US3312130**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:40**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User entered 'VISIT3'	System	19 Oct 2020 15:02:11

**US3312130**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:24:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 15:02:39

**US3312130**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:24:03
User entered '16 Oct 2020'	(b) (4), (b) (6)	19 Oct 2020 15:02:39

**US3312130**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:24:03
User entered '12:50'	(b) (4), (b) (6)	19 Oct 2020 15:02:39

**US3312130**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User entered '16 Oct 2020 12:50'	System	19 Oct 2020 15:02:39

**US3312130**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:24:03
User entered '98.0' F	(b) (4), (b) (6)	19 Oct 2020 15:02:39



**US3312130**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:24:03
User entered 'Oral (Oral)'	(b) (4), (b) (6)	19 Oct 2020 15:02:39

**US3312130**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:24:03
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 15:02:39

**US3312130**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:24:03
User entered '68'	(b) (4), (b) (6)	19 Oct 2020 15:02:39

**US3312130**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User entered 'bpm'	System	19 Oct 2020 15:02:39

**US3312130**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:24:03
User entered '16'	(b) (4), (b) (6)	19 Oct 2020 15:02:39

US3312130

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User entered 'breaths/min'	System	19 Oct 2020 15:02:39

US3312130

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:40

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:24:03
User entered '159'	(b) (4), (b) (6)	19 Oct 2020 15:02:39

US3312130

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User entered 'mmHg'	System	19 Oct 2020 15:02:39



US3312130

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:07:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
User closed query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	04 Feb 2021 09:23:12
Query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'ncs' (Site from System).	Monica Atwood (b) (4) (b) (4)	03 Feb 2021 17:22:41
User opened query 'Diastolic Blood Pressure reported System is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		03 Feb 2021 17:22:28
DataPoint Un-verified.	Monica Atwood (b) (4) (b) (4)	03 Feb 2021 17:22:28
User entered '101' reason for change: Data Entry Error	Monica Atwood (b) (4) (b) (4)	03 Feb 2021 17:22:28
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:24:03
User closed query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	20 Oct 2020 08:24:49
Query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'CORRECT AS ENTERED. NCS. SEE UNSCHEDULED REPEAT VITALS.' (Site from System).	(b) (4), (b) (6)	19 Oct 2020 15:04:51
User opened query 'Diastolic Blood Pressure reported System is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		19 Oct 2020 15:02:39
User entered '107'	(b) (4), (b) (6)	19 Oct 2020 15:02:39

**US3312130**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User entered 'mmHg'	System	19 Oct 2020 15:02:39

**US3312130**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47

**US3312130**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47

**US3312130**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 16:58:40**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:24:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 15:05:44

**US3312130**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 16:58:40**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:24:11
User entered '16 Oct 2020'	(b) (4), (b) (6)	19 Oct 2020 15:05:44

**US3312130**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:58:40**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:24:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 15:05:55

**US3312130**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:58:40**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:24:46
User entered '16 Oct 2020'	(b) (4), (b) (6)	19 Oct 2020 15:05:55



**US3312130**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:58:40**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:24:46
User entered '13:20'	(b) (4), (b) (6)	19 Oct 2020 15:05:55

**US3312130**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:58:40**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User entered '16 Oct 2020 13:20'	System	19 Oct 2020 15:05:55

**US3312130**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:58:40**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:56:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:24:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 15:05:58

**US3312130**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:58:40**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User entered 'I'	System	19 Oct 2020 15:05:58

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:24
Data entry locked.	System	18 Aug 2020 18:14:59
User entered 'Day 64'	System	18 Aug 2020 18:14:59

US3312130

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

[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)	29 Apr 2021 08:03:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-10-19T00:58:44', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '3ebb903e-e4ba-45e8-a4fb-c70184e22974' User entered 'No (N)'	System	19 Oct 2020 05:58:54
	System	19 Oct 2020 05:58:54

US3312130

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

Have you been exposed to someone with 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)	29 Apr 2021 08:03:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-10-19T00:58:47', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '3ebb903e-e4ba-45e8-a4fb-c70184e22974' User entered 'No (N)'	System	19 Oct 2020 05:58:54
	System	19 Oct 2020 05:58:54

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-10-19T00:58:51', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '3ebb903e-e4ba-45e8-a4fb-c70184e22974' User entered '19 Oct 2020 00:58:51'	System	19 Oct 2020 05:58:54
	System	19 Oct 2020 05:58:54



**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:24
Data entry locked.	System	18 Aug 2020 18:14:59
User entered '18 Oct 2020 00:01'	System	18 Aug 2020 18:14:59

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:24
Data entry locked.	System	18 Aug 2020 18:14:59
User entered '22 Oct 2020 23:59'	System	18 Aug 2020 18:14:59

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:24
Data entry locked.	System	18 Aug 2020 18:14:59
User entered 'Day 71'	System	18 Aug 2020 18:14:59

US3312130

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

[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)	29 Apr 2021 08:03:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-10-25T04:13:26', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'fa28ebbc-3c18-4b62-8919-81c25c09a6f4' User entered 'No (N)'	System	25 Oct 2020 09:13:47
	System	25 Oct 2020 09:13:47

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Have you been exposed to someone with 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)	29 Apr 2021 08:03:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-10-25T04:13:41', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'fa28ebbc-3c18-4b62-8919-81c25c09a6f4'	System	25 Oct 2020 09:13:47
User entered 'No (N)'	System	25 Oct 2020 09:13:47

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-10-25T04:13:45', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'fa28ebbc-3c18-4b62-8919-81c25c09a6f4' User entered '25 Oct 2020 04:13:45'	System	25 Oct 2020 09:13:47
	System	25 Oct 2020 09:13:47

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:24
Data entry locked.	System	18 Aug 2020 18:14:59
User entered '25 Oct 2020 00:01'	System	18 Aug 2020 18:14:59

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:24
Data entry locked.	System	18 Aug 2020 18:14:59
User entered '29 Oct 2020 23:59'	System	18 Aug 2020 18:14:59



**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:24
Data entry locked.	System	18 Aug 2020 18:14:59
User entered 'Day 78'	System	18 Aug 2020 18:14:59

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[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)	29 Apr 2021 08:03:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-11-01T00:01:16', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '97cbd719-6015-4e14-952c-30a9c84909cd' User entered 'No (N)'	System	01 Nov 2020 05:01:32
	System	01 Nov 2020 05:01:32

US3312130

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:40

Have you been exposed to someone with 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)	29 Apr 2021 08:03:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-11-01T00:01:20', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '97cbd719-6015-4e14-952c-30a9c84909cd' User entered 'No (N)'	System	01 Nov 2020 05:01:32
	System	01 Nov 2020 05:01:32

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-11-01T00:01:25', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '97cbd719-6015-4e14-952c-30a9c84909cd' User entered '01 Nov 2020 00:01:25'	System	01 Nov 2020 05:01:32
	System	01 Nov 2020 05:01:32

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:24
Data entry locked.	System	18 Aug 2020 18:14:59
User entered '01 Nov 2020 00:01'	System	18 Aug 2020 18:14:59

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:24
Data entry locked.	System	18 Aug 2020 18:14:59
User entered '05 Nov 2020 23:59'	System	18 Aug 2020 18:14:59

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:24
Data entry locked.	System	18 Aug 2020 18:14:59
User entered 'Day 92'	System	18 Aug 2020 18:14:59

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[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)	29 Apr 2021 08:03:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-11-15T00:01:47', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'e08135c2-a9bd-4e6b-ac27-b910adb0b8f0' User entered 'No (N)'	System	15 Nov 2020 06:02:12
	System	15 Nov 2020 06:02:12



**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Have you been exposed to someone with 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)	29 Apr 2021 08:03:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-11-15T00:01:59', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'e08135c2-a9bd-4e6b-ac27-b910adb0b8f0' User entered 'No (N)'	System	15 Nov 2020 06:02:12
	System	15 Nov 2020 06:02:12

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-11-15T00:02:02', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'e08135c2-a9bd-4e6b-ac27-b910adb0b8f0' User entered '15 Nov 2020 00:02:02'	System	15 Nov 2020 06:02:12
	System	15 Nov 2020 06:02:12

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:24
Data entry locked.	System	18 Aug 2020 18:14:59
User entered '15 Nov 2020 00:01'	System	18 Aug 2020 18:14:59

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:24
Data entry locked.	System	18 Aug 2020 18:14:59
User entered '19 Nov 2020 23:59'	System	18 Aug 2020 18:14:59

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 22:15:05

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[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 (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-11-20T10:44:30', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '6171ced7-1d6c-4598-95b7-5fccf4a26082'	System	20 Nov 2020 16:44:41
User entered 'No (N)'	System	20 Nov 2020 16:44:41

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

Have you been exposed to someone with 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 (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-11-20T10:44:33', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '6171ced7-1d6c-4598-95b7-5fccf4a26082'	System	20 Nov 2020 16:44:41
User entered 'No (N)'	System	20 Nov 2020 16:44:41

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-11-20T10:44:38', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '6171ced7-1d6c-4598-95b7-5fccf4a26082' User entered '20 Nov 2020 10:44:38'	System	20 Nov 2020 16:44:41
	System	20 Nov 2020 16:44:41



**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 22:15:05

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[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 (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-11-26T03:46:05', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'a0a1bb78-3365-4cbc-8dda-c15fab7cc93d' User entered 'No (N)'	System	26 Nov 2020 09:46:19
	System	26 Nov 2020 09:46:19

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Have you been exposed to someone with 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 (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-11-26T03:46:11', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'a0a1bb78-3365-4cbc-8dda-c15fab7cc93d'	System	26 Nov 2020 09:46:19
User entered 'No (N)'	System	26 Nov 2020 09:46:19

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-11-26T03:46:14', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'a0a1bb78-3365-4cbc-8dda-c15fab7cc93d' User entered '26 Nov 2020 03:46:14'	System	26 Nov 2020 09:46:19
	System	26 Nov 2020 09:46:19

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 22:15:05



**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 22:15:05

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[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 (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-12-03T05:03:27', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '45dbdb1e-b594-4cbd-8db0-3279708ef17e' User entered 'No (N)'	System	03 Dec 2020 11:03:41
	System	03 Dec 2020 11:03:41

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Have you been exposed to someone with 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 (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-12-03T05:03:34', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '45dbdb1e-b594-4cbd-8db0-3279708ef17e' User entered 'No (N)'	System	03 Dec 2020 11:03:41
	System	03 Dec 2020 11:03:41

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-12-03T05:03:37', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '45dbdb1e-b594-4cbd-8db0-3279708ef17e' User entered '03 Dec 2020 05:03:37'	System	03 Dec 2020 11:03:41
	System	03 Dec 2020 11:03:41

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 22:15:05

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[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 (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-12-10T00:34:59', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'de4dff4d-1143-496a-b6bf-ae2fd1b93c6b' User entered 'No (N)'	System	10 Dec 2020 06:35:13
	System	10 Dec 2020 06:35:13



**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

Have you been exposed to someone with 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 (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-12-10T00:35:04', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'de4dff4d-1143-496a-b6bf-ae2fd1b93c6b'	System	10 Dec 2020 06:35:13
User entered 'No (N)'	System	10 Dec 2020 06:35:13

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-12-10T00:35:10', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'de4dff4d-1143-496a-b6bf-ae2fd1b93c6b' User entered '10 Dec 2020 00:35:10'	System	10 Dec 2020 06:35:13
	System	10 Dec 2020 06:35:13

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 22:15:05

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[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 (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-12-17T04:22:53', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'e7684c60-d6d6-4557-a7c4-b5f700c6d8ce' User entered 'Yes (Y)'	System	17 Dec 2020 10:23:45
	System	17 Dec 2020 10:23:45

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Have you been exposed to someone with 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 (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-12-17T04:23:04', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'e7684c60-d6d6-4557-a7c4-b5f700c6d8ce' User entered 'No (N)'	System	17 Dec 2020 10:23:45
	System	17 Dec 2020 10:23:45

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[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 (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-12-17T04:23:15', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'e7684c60-d6d6-4557-a7c4-b5f700c6d8ce' User entered 'No (N)'	System	17 Dec 2020 10:23:45
	System	17 Dec 2020 10:23:45



**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[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 (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-12-17T04:23:25', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'e7684c60-d6d6-4557-a7c4-b5f700c6d8ce' User entered 'Yes (Y)'	System	17 Dec 2020 10:23:45
	System	17 Dec 2020 10:23:45

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Please 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 (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-12-17T04:23:32', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'e7684c60-d6d6-4557-a7c4-b5f700c6d8ce'	System	17 Dec 2020 10:23:45
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	17 Dec 2020 10:23:45

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-12-17T04:23:36', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'e7684c60-d6d6-4557-a7c4-b5f700c6d8ce' User entered '17 Dec 2020 04:23:36'	System	17 Dec 2020 10:23:45
	System	17 Dec 2020 10:23:45

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 22:15:05

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[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 (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-12-24T00:54:06', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'ea274e88-91d8-43c3-a046-cb83c3e12e37'	System	24 Dec 2020 06:54:16
User entered 'No (N)'	System	24 Dec 2020 06:54:16

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Have you been exposed to someone with 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 (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-12-24T00:54:09', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'ea274e88-91d8-43c3-a046-cb83c3e12e37' User entered 'No (N)'	System	24 Dec 2020 06:54:16
	System	24 Dec 2020 06:54:16



**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2020-12-24T00:54:12', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'ea274e88-91d8-43c3-a046-cb83c3e12e37' User entered '24 Dec 2020 00:54:12'	System	24 Dec 2020 06:54:16
	System	24 Dec 2020 06:54:16

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 22:15:05

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 22:15:05

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 22:15:05



**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 22:15:05

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[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 (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2021-01-14T00:01:17', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'd84b13cf-9372-40a6-ba6c-e8c8976fa376'	System	14 Jan 2021 06:02:06
User entered 'Yes (Y)'	System	14 Jan 2021 06:02:06

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Have you been exposed to someone with 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 (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2021-01-14T00:01:28', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'd84b13cf-9372-40a6-ba6c-e8c8976fa376'	System	14 Jan 2021 06:02:06
User entered 'Yes (Y)'	System	14 Jan 2021 06:02:06

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Please 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 (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2021-01-14T00:01:34', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'd84b13cf-9372-40a6-ba6c-e8c8976fa376'	System	14 Jan 2021 06:02:06
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	14 Jan 2021 06:02:06

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[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 (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2021-01-14T00:01:39', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'd84b13cf-9372-40a6-ba6c-e8c8976fa376'	System	14 Jan 2021 06:02:06
User entered 'No (N)'	System	14 Jan 2021 06:02:06

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[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 (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2021-01-14T00:01:44', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'd84b13cf-9372-40a6-ba6c-e8c8976fa376'	System	14 Jan 2021 06:02:06
User entered 'Yes (Y)'	System	14 Jan 2021 06:02:06

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Please 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 (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2021-01-14T00:01:53', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'd84b13cf-9372-40a6-ba6c-e8c8976fa376'	System	14 Jan 2021 06:02:06
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	14 Jan 2021 06:02:06



**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2021-01-14T00:01:56', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'd84b13cf-9372-40a6-ba6c-e8c8976fa376' User entered '14 Jan 2021 00:01:56'	System	14 Jan 2021 06:02:06
	System	14 Jan 2021 06:02:06

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 22:15:05

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[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 (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2021-01-21T00:01:38', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'b2ca5fdc-0459-45df-ae3e-8f84eb2d95c4'	System	21 Jan 2021 06:02:33
User entered 'Yes (Y)'	System	21 Jan 2021 06:02:33

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Have you been exposed to someone with 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 (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2021-01-21T00:01:42', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'b2ca5fdc-0459-45df-ae3e-8f84eb2d95c4'	System	21 Jan 2021 06:02:33
User entered 'No (N)'	System	21 Jan 2021 06:02:33

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[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 (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2021-01-21T00:01:47', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'b2ca5fdc-0459-45df-ae3e-8f84eb2d95c4'	System	21 Jan 2021 06:02:33
User entered 'Yes (Y)'	System	21 Jan 2021 06:02:33

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2021-01-21T00:02:01', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'b2ca5fdc-0459-45df-ae3e-8f84eb2d95c4' User entered '0'	System	21 Jan 2021 06:02:33



**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2021-01-21T00:02:01', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'b2ca5fdc-0459-45df-ae3e-8f84eb2d95c4'	System	21 Jan 2021 06:02:33
User entered '0'	System	21 Jan 2021 06:02:33

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2021-01-21T00:02:01', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'b2ca5fdc-0459-45df-ae3e-8f84eb2d95c4'	System	21 Jan 2021 06:02:33
User entered '0'	System	21 Jan 2021 06:02:33

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2021-01-21T00:02:01', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'b2ca5fdc-0459-45df-ae3e-8f84eb2d95c4'	System	21 Jan 2021 06:02:33
User entered '0'	System	21 Jan 2021 06:02:33

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2021-01-21T00:02:01', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'b2ca5fdc-0459-45df-ae3e-8f84eb2d95c4'	System	21 Jan 2021 06:02:33
User entered '0'	System	21 Jan 2021 06:02:33

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2021-01-21T00:02:01', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'b2ca5fdc-0459-45df-ae3e-8f84eb2d95c4'	System	21 Jan 2021 06:02:33
User entered '1'	System	21 Jan 2021 06:02:33

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2021-01-21T00:02:01', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'b2ca5fdc-0459-45df-ae3e-8f84eb2d95c4'	System	21 Jan 2021 06:02:33
User entered '1'	System	21 Jan 2021 06:02:33

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2021-01-21T00:02:01', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'b2ca5fdc-0459-45df-ae3e-8f84eb2d95c4'	System	21 Jan 2021 06:02:33
User entered '1'	System	21 Jan 2021 06:02:33

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2021-01-21T00:02:01', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'b2ca5fdc-0459-45df-ae3e-8f84eb2d95c4'	System	21 Jan 2021 06:02:33
User entered '0'	System	21 Jan 2021 06:02:33



**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2021-01-21T00:02:01', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'b2ca5fdc-0459-45df-ae3e-8f84eb2d95c4'	System	21 Jan 2021 06:02:33
User entered '1'	System	21 Jan 2021 06:02:33

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2021-01-21T00:02:01', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'b2ca5fdc-0459-45df-ae3e-8f84eb2d95c4'	System	21 Jan 2021 06:02:33
User entered '0'	System	21 Jan 2021 06:02:33

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2021-01-21T00:02:01', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'b2ca5fdc-0459-45df-ae3e-8f84eb2d95c4'	System	21 Jan 2021 06:02:33
User entered '1'	System	21 Jan 2021 06:02:33

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2021-01-21T00:02:01', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'b2ca5fdc-0459-45df-ae3e-8f84eb2d95c4' User entered '0'	System	21 Jan 2021 06:02:33

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2021-01-21T00:02:01', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'b2ca5fdc-0459-45df-ae3e-8f84eb2d95c4'	System	21 Jan 2021 06:02:33
User entered '1'	System	21 Jan 2021 06:02:33

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2021-01-21T00:02:01', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'b2ca5fdc-0459-45df-ae3e-8f84eb2d95c4'	System	21 Jan 2021 06:02:33
User entered '0'	System	21 Jan 2021 06:02:33

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2021-01-21T00:02:01', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'b2ca5fdc-0459-45df-ae3e-8f84eb2d95c4'	System	21 Jan 2021 06:02:33
User entered '0'	System	21 Jan 2021 06:02:33

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2021-01-21T00:02:01', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'b2ca5fdc-0459-45df-ae3e-8f84eb2d95c4'	System	21 Jan 2021 06:02:33
User entered '1'	System	21 Jan 2021 06:02:33



**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Please 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 (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2021-01-21T00:02:04', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'b2ca5fdc-0459-45df-ae3e-8f84eb2d95c4'	System	21 Jan 2021 06:02:33
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	21 Jan 2021 06:02:33

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[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 (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2021-01-21T00:02:13', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'b2ca5fdc-0459-45df-ae3e-8f84eb2d95c4'	System	21 Jan 2021 06:02:33
User entered 'Yes (Y)'	System	21 Jan 2021 06:02:33

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Please 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 (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2021-01-21T00:02:17', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'b2ca5fdc-0459-45df-ae3e-8f84eb2d95c4'	System	21 Jan 2021 06:02:33
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	21 Jan 2021 06:02:33

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2021-01-21T00:02:21', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'b2ca5fdc-0459-45df-ae3e-8f84eb2d95c4' User entered '21 Jan 2021 00:02:21'	System	21 Jan 2021 06:02:33
	System	21 Jan 2021 06:02:33

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 22:15:05

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[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 (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2021-01-29T06:40:28', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '9352d595-6442-4b0d-b625-7e113733d318'	System	29 Jan 2021 12:40:41
User entered 'No (N)'	System	29 Jan 2021 12:40:41



**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

Have you been exposed to someone with 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 (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2021-01-29T06:40:31', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '9352d595-6442-4b0d-b625-7e113733d318'	System	29 Jan 2021 12:40:41
User entered 'No (N)'	System	29 Jan 2021 12:40:41

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2021-01-29T06:40:34', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '9352d595-6442-4b0d-b625-7e113733d318' User entered '29 Jan 2021 06:40:34'	System	29 Jan 2021 12:40:41

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 22:15:05

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[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 (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2021-02-04T00:56:09', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'e1895a76-3601-4f2e-a5b3-b38418ba6227' User entered 'No (N)'	System	04 Feb 2021 06:56:16
	System	04 Feb 2021 06:56:16

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Have you been exposed to someone with 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 (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2021-02-04T00:56:11', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'e1895a76-3601-4f2e-a5b3-b38418ba6227' User entered 'No (N)'	System	04 Feb 2021 06:56:16
	System	04 Feb 2021 06:56:16

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2021-02-04T00:56:14', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'e1895a76-3601-4f2e-a5b3-b38418ba6227' User entered '04 Feb 2021 00:56:14'	System	04 Feb 2021 06:56:16
	System	04 Feb 2021 06:56:16



**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 22:15:05

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[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 (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2021-02-11T03:46:06', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'd3ddbebe-d2bf-4b50-832f-f13875b963fb' User entered 'No (N)'	System	11 Feb 2021 09:46:16
	System	11 Feb 2021 09:46:16

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

Have you been exposed to someone with 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 (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2021-02-11T03:46:08', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'd3ddbebe-d2bf-4b50-832f-f13875b963fb'	System	11 Feb 2021 09:46:16
User entered 'No (N)'	System	11 Feb 2021 09:46:16

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2021-02-11T03:46:11', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'd3ddbebe-d2bf-4b50-832f-f13875b963fb' User entered '11 Feb 2021 03:46:11'	System	11 Feb 2021 09:46:16
	System	11 Feb 2021 09:46:16

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 22:15:05



**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 22:15:05

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[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 (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2021-02-18T00:01:12', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '23ba2729-2c71-44fe-9645-c5c078f3286a' User entered 'Yes (Y)'	System	18 Feb 2021 06:02:17
	System	18 Feb 2021 06:02:17

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

Have you been exposed to someone with 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 (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2021-02-18T00:01:17', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '23ba2729-2c71-44fe-9645-c5c078f3286a' User entered 'No (N)'	System	18 Feb 2021 06:02:17

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[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 (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2021-02-18T00:01:22', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '23ba2729-2c71-44fe-9645-c5c078f3286a' User entered 'No (N)'	System	18 Feb 2021 06:02:17

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[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 (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2021-02-18T00:01:33', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '23ba2729-2c71-44fe-9645-c5c078f3286a' User entered 'Yes (Y)'	System	18 Feb 2021 06:02:17
	System	18 Feb 2021 06:02:17

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Please 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 (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2021-02-18T00:01:36', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '23ba2729-2c71-44fe-9645-c5c078f3286a'	System	18 Feb 2021 06:02:17
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	18 Feb 2021 06:02:17

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2021-02-18T00:01:39', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '23ba2729-2c71-44fe-9645-c5c078f3286a' User entered '18 Feb 2021 00:01:39'	System	18 Feb 2021 06:02:17
	System	18 Feb 2021 06:02:17

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 22:15:05



**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 22:15:05

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[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 (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2021-02-26T13:40:45-06:00', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '93fa0184-78bc-42f7-afca-3e734548cd16'	System	26 Feb 2021 19:40:59
User entered 'No (N)'	System	26 Feb 2021 19:40:59

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

Have you been exposed to someone with 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 (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2021-02-26T13:40:51-06:00', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '93fa0184-78bc-42f7-afca-3e734548cd16'	System	26 Feb 2021 19:40:59
User entered 'No (N)'	System	26 Feb 2021 19:40:59

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2021-02-26T13:40:54-06:00', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '93fa0184-78bc-42f7-afca-3e734548cd16'	System	26 Feb 2021 19:40:59
User entered '26 Feb 2021 19:40:54'	System	26 Feb 2021 19:40:59

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 22:15:05



**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[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 (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2021-03-04T06:37:54-06:00', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '8645caf6-b594-4cac-8359-50915536d73d'	System	04 Mar 2021 12:38:07
User entered 'No (N)'	System	04 Mar 2021 12:38:07

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

Have you been exposed to someone with 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 (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2021-03-04T06:37:58-06:00', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '8645caf6-b594-4cac-8359-50915536d73d'	System	04 Mar 2021 12:38:07
User entered 'No (N)'	System	04 Mar 2021 12:38:07

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2021-03-04T06:38:02-06:00', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '8645caf6-b594-4cac-8359-50915536d73d' User entered '04 Mar 2021 06:38:02'	System	04 Mar 2021 12:38:07
	System	04 Mar 2021 12:38:07

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 22:15:05

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[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 (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2021-03-11T02:17:56-06:00', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '0c9990c8-6460-43bd-aba3-3b3bfcde14c2'	System	11 Mar 2021 08:18:09
User entered 'No (N)'	System	11 Mar 2021 08:18:09

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

Have you been exposed to someone with 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 (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2021-03-11T02:18:00-06:00', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '0c9990c8-6460-43bd-aba3-3b3bfcde14c2'	System	11 Mar 2021 08:18:09
User entered 'No (N)'	System	11 Mar 2021 08:18:09



**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2021-03-11T02:18:05-06:00', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '0c9990c8-6460-43bd-aba3-3b3bfcde14c2'	System	11 Mar 2021 08:18:09
User entered '11 Mar 2021 02:18:05'	System	11 Mar 2021 08:18:09

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 22:15:05

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[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 (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2021-03-18T00:12:16-05:00', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'aa0c6827-01ee-423e-bb52-b8aefb650afd' User entered 'No (N)'	System	18 Mar 2021 05:12:31
	System	18 Mar 2021 05:12:31

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

Have you been exposed to someone with 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 (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2021-03-18T00:12:22-05:00', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'aa0c6827-01ee-423e-bb52-b8aefb650afd' User entered 'No (N)'	System	18 Mar 2021 05:12:31

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2021-03-18T00:12:25-05:00', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'aa0c6827-01ee-423e-bb52-b8aefb650afd' User entered '18 Mar 2021 00:12:25'	System	18 Mar 2021 05:12:31
	System	18 Mar 2021 05:12:31

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 22:15:05



**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 22:15:05

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[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 (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2021-03-25T07:10:03-05:00', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '4a6efca6-e946-4daf-913e-c45822cd88b8'	System	25 Mar 2021 12:10:13
User entered 'No (N)'	System	25 Mar 2021 12:10:13

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Have you been exposed to someone with 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 (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2021-03-25T07:10:07-05:00', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '4a6efca6-e946-4daf-913e-c45822cd88b8'	System	25 Mar 2021 12:10:13
User entered 'No (N)'	System	25 Mar 2021 12:10:13

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2021-03-25T07:10:10-05:00', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '4a6efca6-e946-4daf-913e-c45822cd88b8' User entered '25 Mar 2021 07:10:10'	System	25 Mar 2021 12:10:13
	System	25 Mar 2021 12:10:13

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 22:15:05



**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[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 (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2021-04-01T00:02:25-05:00', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '9b624443-c696-4510-9b6a-cd9f464695a1' User entered 'No (N)'	System	01 Apr 2021 05:02:39
	System	01 Apr 2021 05:02:39

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

Have you been exposed to someone with 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 (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2021-04-01T00:02:29-05:00', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '9b624443-c696-4510-9b6a-cd9f464695a1'	System	01 Apr 2021 05:02:39
User entered 'No (N)'	System	01 Apr 2021 05:02:39

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2021-04-01T00:02:32-05:00', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '9b624443-c696-4510-9b6a-cd9f464695a1'	System	01 Apr 2021 05:02:39
User entered '01 Apr 2021 00:02:32'	System	01 Apr 2021 05:02:39

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 22:15:05

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[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 (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2021-04-09T05:46:47-05:00', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '6a41efc5-29d0-4658-a6d8-9d50e1cf3343'	System	09 Apr 2021 10:46:56
User entered 'No (N)'	System	09 Apr 2021 10:46:56

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

Have you been exposed to someone with 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 (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2021-04-09T05:46:49-05:00', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '6a41efc5-29d0-4658-a6d8-9d50e1cf3343'	System	09 Apr 2021 10:46:56
User entered 'No (N)'	System	09 Apr 2021 10:46:56



**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2021-04-09T05:46:52-05:00', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '6a41efc5-29d0-4658-a6d8-9d50e1cf3343'	System	09 Apr 2021 10:46:56
User entered '09 Apr 2021 05:46:52'	System	09 Apr 2021 10:46:56

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 22:15:05

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[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 (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2021-04-15T09:37:57-05:00', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '1c6fca20-cb72-49c0-b802-7658ece70b96'	System	15 Apr 2021 14:38:52
User entered 'No (N)'	System	15 Apr 2021 14:38:52

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

Have you been exposed to someone with 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 (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2021-04-15T09:38:06-05:00', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '1c6fca20-cb72-49c0-b802-7658ece70b96'	System	15 Apr 2021 14:38:52
User entered 'No (N)'	System	15 Apr 2021 14:38:52

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2021-04-15T09:38:09-05:00', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '1c6fca20-cb72-49c0-b802-7658ece70b96'	System	15 Apr 2021 14:38:52
User entered '15 Apr 2021 09:38:09'	System	15 Apr 2021 14:38:52

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 22:15:05



**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 22:15:05

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[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 (5AFD137E-8972-41D0-BACA-B6882F3E68A0)', Time: '2021-04-23T13:33:31-05:00', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '04a47955-370b-4fa2-bfe0-564e804241e0'	System	23 Apr 2021 18:33:44
User entered 'No (N)'	System	23 Apr 2021 18:33:44

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Have you been exposed to someone with 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 (5AFD137E-8972-41D0-BACA-B6882F3E68A0)', Time: '2021-04-23T13:33:34-05:00', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '04a47955-370b-4fa2-bfe0-564e804241e0'	System	23 Apr 2021 18:33:44
User entered 'No (N)'	System	23 Apr 2021 18:33:44

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5AFD137E-8972-41D0-BACA-B6882F3E68A0)', Time: '2021-04-23T13:33:38-05:00', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '04a47955-370b-4fa2-bfe0-564e804241e0' User entered '23 Apr 2021 13:33:38'	System	23 Apr 2021 18:33:44
	System	23 Apr 2021 18:33:44

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 22:15:05



**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[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 (5AFD137E-8972-41D0-BACA-B6882F3E68A0)', Time: '2021-04-29T11:15:40-05:00', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'c0ef116f-d098-4709-b8c1-d4ad44262bd1'	System	29 Apr 2021 16:18:58
User entered 'No (N)'	System	29 Apr 2021 16:18:58

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

Have you been exposed to someone with 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 (5AFD137E-8972-41D0-BACA-B6882F3E68A0)', Time: '2021-04-29T11:15:43-05:00', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'c0ef116f-d098-4709-b8c1-d4ad44262bd1'	System	29 Apr 2021 16:18:58
User entered 'No (N)'	System	29 Apr 2021 16:18:58

**US3312130**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5AFD137E-8972-41D0-BACA-B6882F3E68A0)', Time: '2021-04-29T11:15:48-05:00', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: 'c0ef116f-d098-4709-b8c1-d4ad44262bd1'	System	29 Apr 2021 16:18:58
User entered '29 Apr 2021 11:15:48'	System	29 Apr 2021 16:18:58

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 22:15:05



**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 22:15:05



**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 22:15:05



**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 22:15:05



**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 22:15:05



**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 22:15:05



**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 22:15:05



**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 22:15:05



**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 22:15:05



**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 22:15:05



**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 22:15:05



**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 22:15:05



**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 22:15:05



**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 22:15:05



**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 22:15:05



**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 22:15:05



**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 22:15:05



**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 22:15:05



**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 22:15:05



**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 22:15:05



**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 22:15:05



**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 22:15:05



**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 22:15:05



**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 22:15:05



**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 22:15:05



**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 22:15:05



**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 22:15:05



**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 22:15:05



**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 22:15:05



**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '20 Oct 2022 00:01'	System	19 Nov 2020 22:15:05

**US3312130**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:58:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:15:05
Amendment Manager: User entered '24 Oct 2022 23:59'	System	19 Nov 2020 22:15:05

US3312130

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:58:40

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)	29 Apr 2021 15:15:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2021-02-27T16:04:33-06:00', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '3c9b7b39-222e-4c18-9e95-88bb5162990e' User entered 'No (N)'	System	27 Feb 2021 22:04:42
	System	27 Feb 2021 22:04:42

**US3312130**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89A14288-8834-46A9-88BF-E931ADB625AC)', Time: '2021-02-27T16:04:37-06:00', User OID: 'PatientReportedOutcome (US3312130)', ODM File OID: '3c9b7b39-222e-4c18-9e95-88bb5162990e' User entered '27 Feb 2021 22:04:37'	System	27 Feb 2021 22:04:42
	System	27 Feb 2021 22:04:42

**US3312130**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:40**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:20:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:09:51

US3312130

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:58:40

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:20:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User closed query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 05FEB2021 under Participant Decision Visit / OL-D1 in EDC, however same is missing in PPD central lab. Please reconcile the data and amend GCL or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 12:18:35
Query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 05FEB2021 under Participant Decision Visit / OL-D1 in EDC, however same is missing in PPD central lab. Please reconcile the data and amend GCL or Preclarus as appropriate. Thank you.' answered with 'CORRECT AS ENTERED. OL-D1 IN EDC OCCURRED ON 05FEB2021 AND SHIPPED TO PPD' (Site from DM).	Karol Moore (b) (4) (b) (4)	18 Mar 2021 15:37:55
User opened query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 05FEB2021 under Participant Decision Visit / OL-D1 in EDC, however same is missing in PPD central lab. Please reconcile the data and amend GCL or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 11:12:58
User entered '13 Nov 2020'	(b) (4), (b) (6)	16 Nov 2020 16:09:51



**US3312130**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:40**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:20:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:09:51

**US3312130**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:40**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:20:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:09:51

US3312130

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:58:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:20:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 05FEB2021 is recorded under Participant Decision Visit OL-D1/OL-1 visit in PPD Central Lab, however the same is missing in EDC. Please review and update the sample data in EDC as appropriate. Else Clarify, Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 04:55:00
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 05FEB2021 is recorded under Participant Decision Visit OL-D1/OL-1 visit in PPD Central Lab, however the same is missing in EDC. Please review and update the sample data in EDC as appropriate. Else Clarify, Thank you' answered with 'UPDATED IN EDC' (Site from DM).	Karol Moore (b) (4) (b) (4)	18 Mar 2021 15:38:15
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 05FEB2021 is recorded under Participant Decision Visit OL-D1/OL-1 visit in PPD Central Lab, however the same is missing in EDC. Please review and update the sample data in EDC as appropriate. Else Clarify, Thank you' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 11:31:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Nov 2020 16:10:04

**US3312130**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:58:40**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:56:47
User entered 'I'	System	16 Nov 2020 16:10:04

**US3312130**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:40**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:01:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	24 Feb 2021 18:01:39

**US3312130**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:40**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:01:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 18:01:39

**US3312130**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:40**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:01:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 18:01:39

**US3312130**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:40**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:01:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:04
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
	(b) (4)	
User entered 'Occurred during convalescent period.'	(b) (4), (b) (6)	24 Feb 2021 18:01:39



US3312130

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:58:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:01:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Feb 2021 17:58:04

**US3312130**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:58:40**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:01:54
User entered 'I'	System	24 Feb 2021 17:58:04

US3312130

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:58:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:01:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Feb 2021 17:58:30

**US3312130**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:40**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:01:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
	(b) (4)	
User entered '15 Jan 2021'	(b) (4), (b) (6)	24 Feb 2021 17:58:30

**US3312130**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:40**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:01:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	24 Feb 2021 17:58:30

**US3312130**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:40**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:01:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 17:58:30

US3312130

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:58:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:01:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:37
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Feb 2021 17:58:33

**US3312130**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:58:40**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:01:54
User entered 'I'	System	24 Feb 2021 17:58:33



**US3312130**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:40**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:01:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Feb 2021 17:58:53

US3312130

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:58:40

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:01:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
	(b) (4)	
User entered '16 Feb 2021'	(b) (4), (b) (6)	24 Feb 2021 17:58:53

**US3312130**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:40**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:01:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	24 Feb 2021 17:58:53

**US3312130**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:40**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:01:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 17:58:53

US3312130

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:58:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:01:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:40:50
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Feb 2021 17:58:57

**US3312130**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:58:40**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:01:54
User entered 'I'	System	24 Feb 2021 17:58:57

**US3312130**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:40**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:07:25
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:24:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Yes (Y)'	(b) (4)	
	Karol Moore (b) (4)	12 Mar 2021 00:21:15
	(b) (4)	

**US3312130**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:40**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:07:25
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:24:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '05 Mar 2021'	(b) (4)	
	Karol Moore (b) (4)	12 Mar 2021 00:21:15
	(b) (4)	



**US3312130**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:40**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:07:25
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:24:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Clinic (Clinic)'	(b) (4) Karol Moore (b) (4) (b) (4)	12 Mar 2021 00:21:15

**US3312130**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:40**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:07:25
User entered 'VISIT4'	System	12 Mar 2021 00:21:15

**US3312130**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:07:25
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:24:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:28:16

**US3312130**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:07:25
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:24:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:28:16

**US3312130**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:07:25
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:24:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:28:16

**US3312130**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:07:25
User entered empty.	System	29 Mar 2021 19:28:16

US3312130

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:40

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:07:25
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:24:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:28:16

**US3312130**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:07:25
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:24:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:28:16



**US3312130**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:07:25
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:24:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:28:16

**US3312130**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:07:25
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:24:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:28:16

**US3312130**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:07:25
User entered empty.	System	29 Mar 2021 19:28:16

**US3312130**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:07:25
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:24:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:28:16

**US3312130**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:07:25
User entered empty.	System	29 Mar 2021 19:28:16

**US3312130**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:07:25
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:24:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:28:16

**US3312130**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:07:25
User entered empty.	System	29 Mar 2021 19:28:16

**US3312130**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:07:25
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:24:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:28:16



US3312130

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:40

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:07:25
User entered empty.	System	29 Mar 2021 19:28:16

**US3312130**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:07:25

**US3312130**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:07:25

**US3312130**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 16:58:40**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:07:25
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:24:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'No (N)'	(b) (4)	
	Karol Moore (b) (4)	12 Mar 2021 00:21:30
	(b) (4)	

**US3312130**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 16:58:40**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:07:25
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:24:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered empty.	(b) (4)	12 Mar 2021 00:21:30
	Karol Moore (b) (4)	
	(b) (4)	

US3312130

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:58:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:07:25
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:25:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Yes (Y)'	(b) (4)	
	Karol Moore (b) (4)	12 Mar 2021 00:21:41
	(b) (4)	

**US3312130**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:58:40**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:07:25
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:25:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '05 Mar 2021'	(b) (4)	
	Karol Moore (b) (4)	12 Mar 2021 00:21:41
	(b) (4)	

**US3312130**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:58:40**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:07:25
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:25:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '15:20'	(b) (4)	
	Karol Moore (b) (4)	12 Mar 2021 00:21:41
	(b) (4)	



**US3312130**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:58:40**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:07:25
User entered '05 Mar 2021 15:20'	System	12 Mar 2021 00:21:41

**US3312130**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:58:40**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:07:25
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:25:45
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Yes (Y)'	(b) (4)	12 Mar 2021 00:21:47
	Karol Moore (b) (4)	
	(b) (4)	

**US3312130**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:58:40**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:07:25
User entered 'I'	System	12 Mar 2021 00:21:47

**US3312130**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:40**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	29 Apr 2021 15:36:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 12:59:09

**US3312130**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:40**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	29 Apr 2021 15:36:55
User entered '15 Apr 2021'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 12:59:09

**US3312130**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:40**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	29 Apr 2021 15:36:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 12:59:09

**US3312130**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:40**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	29 Apr 2021 15:36:55
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 12:59:09

US3312130

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:58:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:55
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered with 'NA. PAGE ENTERED IN ERROR' (Site from System).	(b) (4), (b) (6)	16 Apr 2021 10:16:17
Query 'Data is required. Please complete.' answered with 'NA. PAGE ENTERED IN ERROR' (Site from System).	Karol Moore (b) (4)	15 Apr 2021 15:27:37
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Apr 2021 17:34:06
User entered empty.	Monica Atwood (b) (4)	14 Apr 2021 17:34:06
	(b) (4)	



**US3312130**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:58:40**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 17:34:06

US3312130

Folder: Covid-19 Assessment 15 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:58:40

[Date of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:15
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User closed query 'Per CDM: It appears that both initial start date of symptoms and Contact date are the same (15Dec 2020). Please review and reconcile.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Mar 2021 12:49:55
Query 'Per CDM: It appears that both initial start date of symptoms and Contact date are the same (15Dec 2020). Please review and reconcile.' answered with 'CORRECT AS ENTERED. SUBJECT BROUGHT IN FOR ILLNESS PER PI ' (Site from DM).	Karol Moore (b) (4) (b) (4)	18 Mar 2021 15:35:27
User opened query 'Per CDM: It appears that both initial start date of symptoms and Contact date are the same (15Dec 2020). Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 22:18:32
User closed query 'Per GCL Lab Reconciliation requery: Swab: Per site response, "updated"; however no updates are reflected in EDC. Kindly consider updating Covid Diagnostic Test eCRF initiated under the corresponding Covid-19 Assessment 15 Dec 2020 eCRF if swab sample was collected on 16-DEC-2020, else clarify.' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 09:44:40
Query 'Per GCL Lab Reconciliation requery: Swab: Per site response, "updated"; however, no updates are reflected in EDC. Kindly consider updating Covid Diagnostic Test eCRF initiated under the corresponding Covid-19 Assessment 15 Dec 2020 eCRF if swab sample was collected on 16-DEC-2020, else clarify.' answered with 'SEE COVID DIAGNOSTIC TEST PAGE. SWAB SAMPLE COLLECTED ON 16DEC2020' (Site from DM).	Karol Moore (b) (4) (b) (4)	29 Dec 2020 17:26:58
User opened query 'Per GCL Lab Reconciliation requery: Swab: Per site response, "updated"; however no updates are reflected in EDC. Kindly consider updating Covid Diagnostic Test eCRF initiated under the corresponding Covid-19 Assessment 15 Dec 2020 eCRF if swab sample was collected on 16-DEC-2020, else clarify.' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 06:07:33

US3312130

Folder: Covid-19 Assessment 15 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:58:40

[Date of Contact](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 16-DEC-2020 is reported under Illness Visit Day 1 in PPD portal; however, swab sample for 16-DEC-2020 is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate under Covid Diagnostic Test eCRF, else clarify. ' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 06:07:33
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 16-DEC-2020 is reported under Illness Visit Day 1 in PPD portal; however, swab sample for 16-DEC-2020 is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate under Covid Diagnostic Test eCRF, else clarify. ' answered with 'UPDATED' (Site from DM).	Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:55:26
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 16-DEC-2020 is reported under Illness Visit Day 1 in PPD portal; however, swab sample for 16-DEC-2020 is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate under Covid Diagnostic Test eCRF, else clarify. ' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 06:19:14
User entered '15 Dec 2020'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 18:45:52

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 16:58:40**

[Time of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:15
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '16:45'	(b) (4) Karol Moore (b) (4) (b) (4)	16 Dec 2020 18:45:52

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 16:58:40**

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
User entered '15 Dec 2020 16:45'	System	16 Dec 2020 18:45:52

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 16:58:40**

[Type of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:15
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Safety Call (Safety Call)'	(b) (4) Karol Moore (b) (4) (b) (4)	16 Dec 2020 18:45:52

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 16:58:40**

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:15
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	16 Dec 2020 18:45:52

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Day 1 (Day 1)'	(b) (4) Karol Moore (b) (4) (b) (4)	16 Dec 2020 18:46:43



**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '15 Dec 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	16 Dec 2020 18:46:43

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	16 Dec 2020 18:46:43

US3312130

Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:58:40

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User closed query 'Per CDM: It appears that O2 Saturation and Temperature were not provided. If not collected, please consider recording as Not Done.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 08:59:43
Query 'Per CDM: It appears that O2 Saturation and Temperature were not provided. If not collected, please consider recording as Not Done.' answered with 'UPDATED' (Site from DM).	Karol Moore (b) (4) (b) (4)	04 Mar 2021 18:37:02
User entered missing code ND - Not Done; reason for change Data Entry Error	Karol Moore (b) (4) (b) (4)	04 Mar 2021 18:36:52
User opened query 'Per CDM: It appears that O2 Saturation and Temperature were not provided. If not collected, please consider recording as Not Done.' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 22:22:32
User entered empty.	Karol Moore (b) (4) (b) (4)	16 Dec 2020 18:46:43

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (1)**

**Generated On: 09 Jun 2021 16:58:40**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
User entered '%'	System	04 Mar 2021 18:36:52
User entered empty.	System	16 Dec 2020 18:46:43

US3312130

Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:58:40

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User closed query ' Per CDM: It appears that "Temperature" is not collected. If not collected, please consider recording these as "Not Done". Thank you!' (Site from DM). Query ' Per CDM: It appears that "Temperature" is not collected. If not collected, please consider recording these as "Not Done". Thank you!' answered with 'UPDATED' (Site from DM). User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6) Karol Moore (b) (4) (b) (4)	08 Mar 2021 13:39:21 04 Mar 2021 18:37:07 04 Mar 2021 18:36:52
User opened query ' Per CDM: It appears that "Temperature" is not collected. If not collected, please consider recording these as "Not Done". Thank you!' (Site from DM). User entered empty.	(b) (4), (b) (6) Karol Moore (b) (4) (b) (4)	04 Feb 2021 08:06:57 16 Dec 2020 18:46:43

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	16 Dec 2020 18:46:43

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	16 Dec 2020 18:46:43

US3312130

Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:58:40

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	16 Dec 2020 18:46:43



US3312130

Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:58:40

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	16 Dec 2020 18:46:43

US3312130

Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:58:40

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	16 Dec 2020 18:46:43

US3312130

Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:58:40

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	16 Dec 2020 18:46:43

US3312130

Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:58:40

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	16 Dec 2020 18:46:43

US3312130

Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:58:40

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	16 Dec 2020 18:46:43

US3312130

Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:58:40

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	16 Dec 2020 18:46:43

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (1)**

**Generated On: 09 Jun 2021 16:58:40**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	16 Dec 2020 18:46:43
	(b) (4)	

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	16 Dec 2020 18:46:43



**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	16 Dec 2020 18:46:43

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	16 Dec 2020 18:46:43

US3312130

Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:58:40

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	16 Dec 2020 18:46:43

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	16 Dec 2020 18:46:43

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	16 Dec 2020 18:46:43

US3312130

Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:58:40

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Day 2 (Day 2)'	(b) (4) Karol Moore (b) (4) (b) (4)	16 Dec 2020 18:47:29

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '16 Dec 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	16 Dec 2020 18:47:29

US3312130

Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:58:40

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	16 Dec 2020 18:47:29



US3312130

Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:58:40

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '99'	(b) (4) Karol Moore (b) (4) (b) (4)	16 Dec 2020 18:47:29

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (2)**

**Generated On: 09 Jun 2021 16:58:40**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
User entered '%'	System	16 Dec 2020 18:47:29

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '98.3' F	(b) (4) Karol Moore (b) (4) (b) (4)	16 Dec 2020 18:47:29

US3312130

Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:58:40

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	16 Dec 2020 18:47:29

US3312130

Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:58:40

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	16 Dec 2020 18:47:29

US3312130

Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:58:40

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	16 Dec 2020 18:47:29

US3312130

Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:58:40

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	16 Dec 2020 18:47:29

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	16 Dec 2020 18:47:29



**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	16 Dec 2020 18:47:29

US3312130

Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:58:40

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	16 Dec 2020 18:47:29

US3312130

Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:58:40

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	16 Dec 2020 18:47:29

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (2)**

**Generated On: 09 Jun 2021 16:58:40**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	16 Dec 2020 18:47:29

US3312130

Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:58:40

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	16 Dec 2020 18:47:29

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	16 Dec 2020 18:47:29

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	16 Dec 2020 18:47:29

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	16 Dec 2020 18:47:29



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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:58:40

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	16 Dec 2020 18:47:29

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	16 Dec 2020 18:47:29

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	16 Dec 2020 18:47:29

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (3)**

**Generated On: 09 Jun 2021 16:58:40**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Day 3 (Day 3)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:51:09

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (3)**

**Generated On: 09 Jun 2021 16:58:40**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '17 Dec 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:51:09

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (3)**

**Generated On: 09 Jun 2021 16:58:40**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:51:09

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (3)**

**Generated On: 09 Jun 2021 16:58:40**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:51:09

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (3)**

**Generated On: 09 Jun 2021 16:58:40**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
User entered '%'	System	22 Dec 2020 17:51:09



**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (3)**

**Generated On: 09 Jun 2021 16:58:40**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '98.9' F	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:51:09

US3312130

Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:58:40

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4)	22 Dec 2020 17:51:09
	Karol Moore (b) (4)	
	(b) (4)	

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:58:40

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:51:09

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:58:40

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:51:09

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:58:40

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:51:09

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:58:40

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:51:09

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (3)**

**Generated On: 09 Jun 2021 16:58:40**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:51:09

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:58:40

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:51:09



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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:58:40

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4)	22 Dec 2020 17:51:09
	Karol Moore (b) (4)	
	(b) (4)	

US3312130

Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:58:40

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:51:09

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (3)**

**Generated On: 09 Jun 2021 16:58:40**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:51:09

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (3)**

**Generated On: 09 Jun 2021 16:58:40**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:51:09

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (3)**

**Generated On: 09 Jun 2021 16:58:40**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:51:09

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (3)**

**Generated On: 09 Jun 2021 16:58:40**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:51:09

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (3)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:51:09

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (3)**

**Generated On: 09 Jun 2021 16:58:40**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:51:09



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**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (3)**

**Generated On: 09 Jun 2021 16:58:40**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:51:09

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (4)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Day 4 (Day 4)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:51:39

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (4)**

**Generated On: 09 Jun 2021 16:58:40**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '18 Dec 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:51:39

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**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (4)**

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:51:39

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**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (4)**

**Generated On: 09 Jun 2021 16:58:40**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '100'	(b) (4)	
	Karol Moore (b) (4)	22 Dec 2020 17:51:39
	(b) (4)	

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**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (4)**

**Generated On: 09 Jun 2021 16:58:40**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
User entered '%'	System	22 Dec 2020 17:51:39

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:58:40

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '98.8' F	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:51:39

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:58:40

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:51:39



**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (4)**

**Generated On: 09 Jun 2021 16:58:40**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4)	22 Dec 2020 17:51:39
	Karol Moore (b) (4)	
	(b) (4)	

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:58:40

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:51:39

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:58:40

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:51:39

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:58:40

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	22 Dec 2020 17:51:39
	(b) (4)	

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:58:40

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:51:39

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:58:40

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:51:39

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:58:40

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4)	22 Dec 2020 17:51:39
	Karol Moore (b) (4)	
	(b) (4)	

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:58:40

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:51:39



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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:58:40

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:51:39

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**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (4)**

**Generated On: 09 Jun 2021 16:58:40**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:51:39

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:58:40

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:51:39

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**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (4)**

**Generated On: 09 Jun 2021 16:58:40**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:51:39

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:58:40

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:51:39

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**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (4)**

**Generated On: 09 Jun 2021 16:58:40**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4)	22 Dec 2020 17:51:39
	Karol Moore (b) (4)	
	(b) (4)	

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:58:40

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:51:39

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**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (5)**

**Generated On: 09 Jun 2021 16:58:40**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Day 5 (Day 5)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:52:08



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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:58:40

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '19 Dec 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:52:08

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:58:40

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '0'	(b) (4)	
	Karol Moore (b) (4)	22 Dec 2020 17:52:08
	(b) (4)	

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**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (5)**

**Generated On: 09 Jun 2021 16:58:40**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '98'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:52:08

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (5)

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
User entered '%'	System	22 Dec 2020 17:52:08

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**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (5)**

**Generated On: 09 Jun 2021 16:58:40**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '97.5' F	(b) (4)	
	Karol Moore (b) (4)	22 Dec 2020 17:52:08
	(b) (4)	

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:58:40

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:52:08

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**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (5)**

**Generated On: 09 Jun 2021 16:58:40**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4)	22 Dec 2020 17:52:08
	Karol Moore (b) (4)	
	(b) (4)	

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:58:40

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:52:08



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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:58:40

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:52:08

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:58:40

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4)	22 Dec 2020 17:52:08
	Karol Moore (b) (4)	
	(b) (4)	

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**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (5)**

**Generated On: 09 Jun 2021 16:58:40**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:52:08

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:58:40

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:52:08

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:58:40

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4)	22 Dec 2020 17:52:08
	Karol Moore (b) (4)	
	(b) (4)	

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:58:40

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:52:08

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:58:40

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:52:08

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**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (5)**

**Generated On: 09 Jun 2021 16:58:40**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:52:08



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**Form: Symptom Log (5)**

**Generated On: 09 Jun 2021 16:58:40**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:52:08

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**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (5)**

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:52:08

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (5)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:52:08

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:58:40

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:52:08

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:58:40

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:52:08

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**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (6)**

**Generated On: 09 Jun 2021 16:58:40**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Day 6 (Day 6)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:52:40

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (6)**

**Generated On: 09 Jun 2021 16:58:40**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '20 Dec 2020'	(b) (4)	
	Karol Moore (b) (4)	22 Dec 2020 17:52:40
	(b) (4)	

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**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (6)**

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '0'	(b) (4)	22 Dec 2020 17:52:40
	Karol Moore (b) (4)	
	(b) (4)	



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**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (6)**

**Generated On: 09 Jun 2021 16:58:40**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '98'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:52:40

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**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (6)**

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
User entered '%'	System	22 Dec 2020 17:52:40

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**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (6)**

**Generated On: 09 Jun 2021 16:58:40**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '97.1' F	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:52:40

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**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (6)**

**Generated On: 09 Jun 2021 16:58:40**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:52:40

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:58:40

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	22 Dec 2020 17:52:40
	(b) (4)	

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:58:40

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:52:40

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Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:58:40

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:52:40

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Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:58:40

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4)	22 Dec 2020 17:52:40
	Karol Moore (b) (4)	
	(b) (4)	



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**Form: Symptom Log (6)**

**Generated On: 09 Jun 2021 16:58:40**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:52:40

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:58:40

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:52:40

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:58:40

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4)	22 Dec 2020 17:52:40
	Karol Moore (b) (4)	
	(b) (4)	

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:58:40

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:52:40

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:58:40

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:52:40

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**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (6)**

**Generated On: 09 Jun 2021 16:58:40**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:52:40

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**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (6)**

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:52:40

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Form: Symptom Log (6)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:52:40



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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:58:40

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:52:40

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:58:40

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:52:40

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:58:40

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:52:40

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**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (7)**

**Generated On: 09 Jun 2021 16:58:40**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Day 7 (Day 7)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:53:48

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (7)**

**Generated On: 09 Jun 2021 16:58:40**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '21 Dec 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:53:48

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**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (7)**

**Generated On: 09 Jun 2021 16:58:40**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:53:48

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**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (7)**

**Generated On: 09 Jun 2021 16:58:40**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '99'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:53:48

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (7)**

**Generated On: 09 Jun 2021 16:58:40**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
User entered '%'	System	22 Dec 2020 17:53:48



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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:58:40

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '97.4' F	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:53:48

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**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (7)**

**Generated On: 09 Jun 2021 16:58:40**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4)	22 Dec 2020 17:53:48
	Karol Moore (b) (4)	
	(b) (4)	

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**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (7)**

**Generated On: 09 Jun 2021 16:58:40**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:53:48

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:58:40

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:53:48

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:58:40

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:53:48

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (7)**

**Generated On: 09 Jun 2021 16:58:40**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:53:48

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (7)**

**Generated On: 09 Jun 2021 16:58:40**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:53:48

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:58:40

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:53:48



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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:58:40

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:53:48

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:58:40

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:53:48

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:58:40

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:53:48

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (7)**

**Generated On: 09 Jun 2021 16:58:40**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:53:48

US3312130

Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:58:40

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:53:48

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**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (7)**

**Generated On: 09 Jun 2021 16:58:40**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:53:48

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:58:40

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:53:48

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (7)**

**Generated On: 09 Jun 2021 16:58:40**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:53:48



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**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (7)**

**Generated On: 09 Jun 2021 16:58:40**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	22 Dec 2020 17:53:48
	(b) (4)	

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**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (8)**

**Generated On: 09 Jun 2021 16:58:40**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Day 8 (Day 8)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Dec 2020 20:54:14

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:58:40

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '22 Dec 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Dec 2020 20:54:14

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**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (8)**

**Generated On: 09 Jun 2021 16:58:40**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Dec 2020 20:54:14

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:58:40

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '99'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Dec 2020 20:54:14

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**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (8)**

**Generated On: 09 Jun 2021 16:58:40**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
User entered '%'	System	28 Dec 2020 20:54:14

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**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (8)**

**Generated On: 09 Jun 2021 16:58:40**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '97.8' F	(b) (4) Karol Moore (b) (4) (b) (4)	28 Dec 2020 20:54:14

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (8)**

**Generated On: 09 Jun 2021 16:58:40**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4)	28 Dec 2020 20:54:14
	Karol Moore (b) (4)	
	(b) (4)	



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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:58:40

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	28 Dec 2020 20:54:14
	(b) (4)	

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:58:40

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Dec 2020 20:54:14

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:58:40

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4)	28 Dec 2020 20:54:14
	Karol Moore (b) (4)	
	(b) (4)	

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:58:40

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Dec 2020 20:54:14

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:58:40

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Dec 2020 20:54:14

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:58:40

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Dec 2020 20:54:14

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:58:40

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Dec 2020 20:54:14

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**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (8)**

**Generated On: 09 Jun 2021 16:58:40**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Dec 2020 20:54:14



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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:58:40

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Dec 2020 20:54:14

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**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (8)**

**Generated On: 09 Jun 2021 16:58:40**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Dec 2020 20:54:14

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**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (8)**

**Generated On: 09 Jun 2021 16:58:40**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Dec 2020 20:54:14

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:58:40

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	28 Dec 2020 20:54:14
	(b) (4)	

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:58:40

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Dec 2020 20:54:14

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**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (8)**

**Generated On: 09 Jun 2021 16:58:40**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4)	28 Dec 2020 20:54:14
	Karol Moore (b) (4)	
	(b) (4)	

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:58:40

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Dec 2020 20:54:14

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:58:40

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Day 9 (Day 9)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Dec 2020 20:54:41



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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:58:40

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '23 Dec 2020'	(b) (4)	
	Karol Moore (b) (4)	28 Dec 2020 20:54:41
	(b) (4)	

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**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (9)**

**Generated On: 09 Jun 2021 16:58:40**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '0'	(b) (4)	28 Dec 2020 20:54:41
	Karol Moore (b) (4)	
	(b) (4)	

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (9)**

**Generated On: 09 Jun 2021 16:58:40**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '97'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Dec 2020 20:54:41

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (9)**

**Generated On: 09 Jun 2021 16:58:40**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
User entered '%'	System	28 Dec 2020 20:54:41

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (9)**

**Generated On: 09 Jun 2021 16:58:40**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '97.4' F	(b) (4)	
	Karol Moore (b) (4)	28 Dec 2020 20:54:41
	(b) (4)	

US3312130

Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:58:40

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	28 Dec 2020 20:54:41
	(b) (4)	

US3312130

Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:58:40

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	28 Dec 2020 20:54:41
	(b) (4)	

US3312130

Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:58:40

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Dec 2020 20:54:41



US3312130

Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:58:40

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	28 Dec 2020 20:54:41
	(b) (4)	

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (9)**

**Generated On: 09 Jun 2021 16:58:40**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	28 Dec 2020 20:54:41
	(b) (4)	

US3312130

Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:58:40

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Dec 2020 20:54:41

US3312130

Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:58:40

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	28 Dec 2020 20:54:41
	(b) (4)	

US3312130

Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:58:40

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Dec 2020 20:54:41

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (9)**

**Generated On: 09 Jun 2021 16:58:40**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Dec 2020 20:54:41

US3312130

Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:58:40

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Dec 2020 20:54:41

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (9)**

**Generated On: 09 Jun 2021 16:58:40**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Dec 2020 20:54:41



**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (9)**

**Generated On: 09 Jun 2021 16:58:40**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Dec 2020 20:54:41

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (9)**

**Generated On: 09 Jun 2021 16:58:40**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Dec 2020 20:54:41

US3312130

Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:58:40

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Dec 2020 20:54:41

US3312130

Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:58:40

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Dec 2020 20:54:41

US3312130

Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:58:40

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	28 Dec 2020 20:54:41
	(b) (4)	

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:58:40

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Day 10 (Day 10)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Dec 2020 20:55:48

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (10)**

**Generated On: 09 Jun 2021 16:58:40**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '24 Dec 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Dec 2020 20:55:48

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (10)**

**Generated On: 09 Jun 2021 16:58:40**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Dec 2020 20:55:48



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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:58:40

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '98'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Dec 2020 20:55:48

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (10)**

**Generated On: 09 Jun 2021 16:58:40**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
User entered '%'	System	28 Dec 2020 20:55:48

US3312130

Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:58:40

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '98.1' F	(b) (4) Karol Moore (b) (4) (b) (4)	28 Dec 2020 20:55:48

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (10)**

**Generated On: 09 Jun 2021 16:58:40**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	28 Dec 2020 20:55:48
	(b) (4)	

US3312130

Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:58:40

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	28 Dec 2020 20:55:48
	(b) (4)	

US3312130

Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:58:40

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Dec 2020 20:55:48

US3312130

Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:58:40

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Dec 2020 20:55:48

US3312130

Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:58:40

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4)	28 Dec 2020 20:55:48
	Karol Moore (b) (4)	
	(b) (4)	



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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:58:40

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Dec 2020 20:55:48

US3312130

Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:58:40

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	28 Dec 2020 20:55:48
	(b) (4)	

US3312130

Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:58:40

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4)	28 Dec 2020 20:55:48
	Karol Moore (b) (4)	
	(b) (4)	

US3312130

Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:58:40

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4)	
	Karol Moore (b) (4)	28 Dec 2020 20:55:48
	(b) (4)	

US3312130

Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:58:40

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Dec 2020 20:55:48

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (10)**

**Generated On: 09 Jun 2021 16:58:40**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4)	28 Dec 2020 20:55:48
	Karol Moore (b) (4)	
	(b) (4)	

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (10)**

**Generated On: 09 Jun 2021 16:58:40**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Dec 2020 20:55:48

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Symptom Log (10)**

**Generated On: 09 Jun 2021 16:58:40**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Dec 2020 20:55:48



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Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:58:40

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Dec 2020 20:55:48

US3312130

Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:58:40

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Dec 2020 20:55:48

US3312130

Folder: Covid-19 Assessment 15 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:58:40

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Dec 2020 20:55:48

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: COVID Diagnostic Test**

**Generated On: 09 Jun 2021 16:58:40**

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:58
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:22:48
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '16 Dec 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Dec 2020 20:56:10

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: COVID Diagnostic Test**

**Generated On: 09 Jun 2021 16:58:40**

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:58
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:22:48
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Dec 2020 20:56:10

US3312130

Folder: Covid-19 Assessment 15 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:58:40

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:58
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:22:48
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4) (b) (4), (b) (6)	22 Jan 2021 03:32:53
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'confirmed' (Site from System).	(b) (4), (b) (6)	20 Jan 2021 17:53:10
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	20 Jan 2021 17:53:00
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Jan 2021 17:53:00
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	28 Dec 2020 20:56:10

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**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: COVID Diagnostic Test**

**Generated On: 09 Jun 2021 16:58:40**

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:58
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:22:48
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '16 Dec 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Dec 2020 20:56:10

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: COVID Diagnostic Test**

**Generated On: 09 Jun 2021 16:58:40**

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:58
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:22:48
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Dec 2020 20:56:10



**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: COVID Diagnostic Test**

**Generated On: 09 Jun 2021 16:58:40**

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:58
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:22:48
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered empty.	(b) (4)	28 Dec 2020 20:56:10
	Karol Moore (b) (4)	
	(b) (4)	

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**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: COVID Diagnostic Test**

**Generated On: 09 Jun 2021 16:58:40**

[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)	02 May 2021 02:21:58
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:22:48
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Dec 2020 20:56:10

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**Folder: Covid-19 Assessment 15 Dec 2020**

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[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:58
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:22:48
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered empty.	(b) (4)	28 Dec 2020 20:56:10
	Karol Moore (b) (4)	
	(b) (4)	

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**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: COVID Diagnostic Test**

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[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:58
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:22:48
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered empty.	(b) (4)	28 Dec 2020 20:56:10
	Karol Moore (b) (4)	
	(b) (4)	

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**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: COVID Diagnostic Test**

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[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:21:58
User entered '1'	System	20 Jan 2021 17:53:00
User entered '0'	System	28 Dec 2020 20:56:10

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Folder: Covid-19 Assessment 15 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:58:40

Did the subject have Respiratory Rates  $\geq 30$  per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:22:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:23:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:53:43

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**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 09 Jun 2021 16:58:40**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:22:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:23:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:53:43

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**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 09 Jun 2021 16:58:40**

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:22:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:23:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:53:43



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[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:22:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:23:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:53:43

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Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:58:40

Did the subject have Heart Rate  $\geq$  125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:22:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:23:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:53:43

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**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 09 Jun 2021 16:58:40**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:22:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:23:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:53:43

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**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 09 Jun 2021 16:58:40**

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:22:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:23:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:53:43

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[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:22:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:23:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:53:43

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Did the subject have Oxygen Saturation of SpO2  $\leq$  93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:22:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:23:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:53:43

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**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 09 Jun 2021 16:58:40**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:22:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:23:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:53:43

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**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 09 Jun 2021 16:58:40**

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:22:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:23:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:53:43



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[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:22:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:23:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:53:43

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Folder: Covid-19 Assessment 15 Dec 2020

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Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:22:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:23:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:53:43

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**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 09 Jun 2021 16:58:40**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:22:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:23:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:53:43

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**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 09 Jun 2021 16:58:40**

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:22:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:23:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:53:43

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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:22:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:23:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:53:43

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**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 09 Jun 2021 16:58:40**

[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:22:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:23:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:53:43

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**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 09 Jun 2021 16:58:40**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:22:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:23:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:53:43

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Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:58:40

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:22:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:23:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	20 Jan 2021 17:53:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Jan 2021 17:53:52
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Jan 2021 17:53:52
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Jan 2021 17:53:43
User entered empty.	(b) (4), (b) (6)	20 Jan 2021 17:53:43



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**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 09 Jun 2021 16:58:40**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:22:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:23:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:53:43

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**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 09 Jun 2021 16:58:40**

[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:22:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:23:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:53:43

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**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 09 Jun 2021 16:58:40**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:22:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:23:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:53:43

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**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 09 Jun 2021 16:58:40**

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:22:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:23:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:53:43

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**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 09 Jun 2021 16:58:40**

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:22:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:23:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:53:43

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**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 09 Jun 2021 16:58:40**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:22:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:23:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:53:43

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**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 09 Jun 2021 16:58:40**

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:22:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:23:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:53:43

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**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 09 Jun 2021 16:58:40**

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:22:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:23:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:53:43



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**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 09 Jun 2021 16:58:40**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:22:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:23:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:53:43

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**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 09 Jun 2021 16:58:40**

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:22:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:23:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:53:43

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[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:22:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:23:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:53:43

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**Generated On: 09 Jun 2021 16:58:40**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:22:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:23:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:53:43

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

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**Generated On: 09 Jun 2021 16:58:40**

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:22:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:23:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:53:43

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**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Covid-19 Severity Assessment**

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[Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:22:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:23:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:53:43

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**Folder: Covid-19 Assessment 15 Dec 2020**

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**Generated On: 09 Jun 2021 16:58:40**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:22:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:23:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:53:43

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 09 Jun 2021 16:58:40**

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:22:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:23:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:53:43



US3312130

Folder: Covid-19 Assessment 15 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:58:40

[Evidence of Shock Requires  
Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:22:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:23:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:53:43

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 09 Jun 2021 16:58:40**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:22:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:23:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:53:43

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 09 Jun 2021 16:58:40**

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:22:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:23:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:53:43

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 09 Jun 2021 16:58:40**

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:22:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:23:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:53:43

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 09 Jun 2021 16:58:40**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:22:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:23:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:53:43

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 09 Jun 2021 16:58:40**

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:22:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:23:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:53:43

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 09 Jun 2021 16:58:40**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:22:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:23:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:53:43

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 09 Jun 2021 16:58:40**

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:22:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:23:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:53:43



**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 09 Jun 2021 16:58:40**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:22:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:23:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:53:43

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 09 Jun 2021 16:58:40**

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:22:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:23:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:53:43

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 09 Jun 2021 16:58:40**

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:22:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:23:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:53:43

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 09 Jun 2021 16:58:40**

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:22:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:23:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:53:43

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 09 Jun 2021 16:58:40**

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:22:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:23:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:53:43

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 09 Jun 2021 16:58:40**

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:22:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:23:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:53:43

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 09 Jun 2021 16:58:40**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:22:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:23:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:53:43

**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 09 Jun 2021 16:58:40**

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:22:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:23:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:53:43



**US3312130**

**Folder: Covid-19 Assessment 15 Dec 2020**

**Form: Generate Next COVID-19 Assessment**

**Generated On: 09 Jun 2021 16:58:40**

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:22:09
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:23:13
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'No (N)'	(b) (4)	28 Dec 2020 20:56:15
	Karol Moore (b) (4)	
	(b) (4)	

**US3312130**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:54:23

**US3312130**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:17:57
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:54:23

**US3312130**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:17:57
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '18 Dec 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:54:23

**US3312130**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	(b) (4), (b) (6)	22 Dec 2020 17:54:32

**US3312130**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:17:57
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:54:32

**US3312130**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:17:57
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '20 Dec 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:54:32

**US3312130**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 09 Jun 2021 16:58:40**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Karol Moore (b) (4) [REDACTED]	28 Dec 2020 20:56:41



**US3312130**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 09 Jun 2021 16:58:40**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:17:57
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Dec 2020 20:56:41

**US3312130**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 09 Jun 2021 16:58:40**

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:17:57
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '22 Dec 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Dec 2020 20:56:41

**US3312130**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 09 Jun 2021 16:58:40**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Karol Moore (b) (4) (b) (4)	15 Jan 2021 14:31:49

**US3312130**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 09 Jun 2021 16:58:40**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:17:57
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	15 Jan 2021 14:31:49

**US3312130**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 09 Jun 2021 16:58:40**

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:17:57
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	15 Jan 2021 14:31:49

**US3312130**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 16:58:40**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Karol Moore (b) (4) (b) (4)	15 Jan 2021 14:31:49

**US3312130**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 16:58:40**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:17:57
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'No (N)'	(b) (4)	15 Jan 2021 14:31:49
	Karol Moore (b) (4)	
	(b) (4)	

**US3312130**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 16:58:40**

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:17:57
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	15 Jan 2021 14:31:49



**US3312130**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 09 Jun 2021 16:58:40**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Karol Moore (b) (4) (b) (4)	15 Jan 2021 14:31:49

**US3312130**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 09 Jun 2021 16:58:40**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:17:57
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	15 Jan 2021 14:31:49

**US3312130**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 09 Jun 2021 16:58:40**

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:17:57
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	15 Jan 2021 14:31:49

US3312130

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 16:58:40

[Visit](#)

Audit	User	Time (GMT)
User closed query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 28 sample with Accession # 1F653271276 is reported with 14JAN2021 Date of Collection however in EDC is marked as No. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend EDC or Preclarus Thank you.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 12:43:29
Query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 28 sample with Accession # 1F653271276 is reported with 14JAN2021 Date of Collection however in EDC is marked as No. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend EDC or Preclarus Thank you.' answered with 'UPDATED' (Site from DM).	Karol Moore (b) (4) (b) (4)	18 Mar 2021 15:36:28
User opened query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 28 sample with Accession # 1F653271276 is reported with 14JAN2021 Date of Collection however in EDC is marked as No. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend EDC or Preclarus Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 07:49:30
User accepted default value 'Day 28 (Day 28)'	Karol Moore (b) (4) (b) (4)	15 Jan 2021 14:31:49

**US3312130**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 16:58:40**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:17:57
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	18 Mar 2021 15:36:22
User entered 'No (N)'	Karol Moore (b) (4)	15 Jan 2021 14:31:49
	(b) (4)	

**US3312130**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 16:58:40**

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:17:57
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '14 Jan 2021' reason for change: Data Entry Error	(b) (4)	18 Mar 2021 15:36:22
User entered empty.	Karol Moore (b) (4)	15 Jan 2021 14:31:49
	(b) (4)	

**US3312130**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:40**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:23:12
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Yes (Y)'	Karol Moore (b) (4)	16 Dec 2020 18:49:45

**US3312130**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:40**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:23:12
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '16 Dec 2020'	(b) (4)	
	Karol Moore (b) (4)	16 Dec 2020 18:49:45
	(b) (4)	



**US3312130**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:40**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:23:12
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Clinic (Clinic)'	Karol Moore (b) (4)	16 Dec 2020 18:49:45

**US3312130**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:40**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:56
User entered 'SICKD1'	System	16 Dec 2020 18:49:45

US3312130

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:22:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Yes (Y)'	(b) (4)	
	Karol Moore (b) (4)	16 Dec 2020 18:50:45
	(b) (4)	

US3312130

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:22:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '16 Dec 2020'	(b) (4)	
	Karol Moore (b) (4)	16 Dec 2020 18:50:45
	(b) (4)	

**US3312130**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:22:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '11:33'	(b) (4)	
	Karol Moore (b) (4)	16 Dec 2020 18:50:45
	(b) (4)	

**US3312130**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:56
User entered '16 Dec 2020 11:33'	System	16 Dec 2020 18:50:45

**US3312130**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:22:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '69' in	Karol Moore (b) (4)	16 Dec 2020 18:50:45
DataPoint set to visible.	System	16 Dec 2020 18:49:45

US3312130

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:40

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:22:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '207' lb	(b) (4) Karol Moore (b) (4)	16 Dec 2020 18:50:45
DataPoint set to visible.	(b) (4) System	16 Dec 2020 18:49:45



US3312130

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:40

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:22:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '98.3' F	(b) (4)	
	Karol Moore (b) (4)	16 Dec 2020 18:50:45
	(b) (4)	

**US3312130**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:22:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Oral (Oral)'	(b) (4)	
	Karol Moore (b) (4)	16 Dec 2020 18:50:45
	(b) (4)	

**US3312130**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:22:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered empty.	(b) (4)	16 Dec 2020 18:50:45
	Karol Moore (b) (4)	
	(b) (4)	

**US3312130**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:22:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '79'	(b) (4)	
	Karol Moore (b) (4)	16 Dec 2020 18:50:45
	(b) (4)	

**US3312130**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:56
User entered 'bpm'	System	16 Dec 2020 18:50:45

**US3312130**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:22:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '14'	(b) (4)	
	Karol Moore (b) (4)	16 Dec 2020 18:50:45
	(b) (4)	

US3312130

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:56
User entered 'breaths/min'	System	16 Dec 2020 18:50:45

US3312130

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:40

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:22:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '172' reason for change: Data Entry Error	(b) (4)	
	Monica Atwood (b) (4)	03 Feb 2021 17:19:02
User entered '175'	(b) (4)	
	Karol Moore (b) (4)	16 Dec 2020 18:50:45
	(b) (4)	



**US3312130**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:56
User entered 'mmHg'	System	16 Dec 2020 18:50:45

US3312130

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:22:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User closed query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	04 Feb 2021 09:21:26
Query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'ncs ae is entered' (Site from System).	Monica Atwood (b) (4) (b) (4)	03 Feb 2021 17:19:28
User opened query 'Diastolic Blood Pressure reported System is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		03 Feb 2021 17:19:02
User entered '110' reason for change: Data Entry Error	Monica Atwood (b) (4) (b) (4)	03 Feb 2021 17:19:02
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	17 Dec 2020 14:20:44
User closed query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	17 Dec 2020 14:20:25
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS. CONFIRMED CORRECT AS ENTERED' (Site from System).	Karol Moore (b) (4) (b) (4)	16 Dec 2020 18:51:27
Query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS. CONFIRMED CORRECT AS ENTERED' (Site from System).	Karol Moore (b) (4) (b) (4)	16 Dec 2020 18:51:17
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		16 Dec 2020 18:50:45

US3312130

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User opened query 'Diastolic Blood Pressure reported System is out of range &gt; 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). User entered '115'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 18:50:45 16 Dec 2020 18:50:45

**US3312130**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:56
User entered 'mmHg'	System	16 Dec 2020 18:50:45

**US3312130**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:56

**US3312130**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:56

**US3312130**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 16:58:40**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:19:48
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Yes (Y)'	Karol Moore (b) (4)	16 Dec 2020 18:51:37

**US3312130**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 16:58:40**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:19:48
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '16 Dec 2020'	(b) (4)	
	Karol Moore (b) (4)	16 Dec 2020 18:51:37
	(b) (4)	



**US3312130**

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 09 Jun 2021 16:58:40**

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:18:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Yes (Y)'	(b) (4)	
	Karol Moore (b) (4)	16 Dec 2020 18:51:47
	(b) (4)	

US3312130

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 16:58:40

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:48:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:18:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 16 DEC 2020 is recorded under illness Visit Day 1 visit in EDC, however the same SARS-CoV-2 serum sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Dec 2020 11:50:19
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 16 DEC 2020 is recorded under illness Visit Day 1 visit in EDC, however the same SARS-CoV-2 serum sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'CONFIRMED. ACCESSION NUMBER: 1F69931' (Site from DM).	Karol Moore (b) (4) (b) (4)	22 Dec 2020 17:56:29
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 16 DEC 2020 is recorded under illness Visit Day 1 visit in EDC, however the same SARS-CoV-2 serum sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 07:01:55
User entered '16 Dec 2020'	Karol Moore (b) (4) (b) (4)	16 Dec 2020 18:51:47

**US3312130**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:40**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:44:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Yes (Y)'	(b) (4)	
	Karol Moore (b) (4)	15 Jan 2021 14:27:34
	(b) (4)	

**US3312130**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:40**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:44:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '14 Jan 2021'	(b) (4)	
	Karol Moore (b) (4)	15 Jan 2021 14:27:34
	(b) (4)	

**US3312130**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:40**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:44:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Clinic (Clinic)'	(b) (4) Karol Moore (b) (4) (b) (4)	15 Jan 2021 14:27:34

**US3312130**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:40**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:01
User entered 'SICKD28'	System	15 Jan 2021 14:27:34

**US3312130**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:44:45
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Yes (Y)'	(b) (4)	15 Jan 2021 14:28:14
	Karol Moore (b) (4)	
	(b) (4)	

US3312130

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:44:45
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '14 Jan 2021'	(b) (4)	
	Karol Moore (b) (4)	15 Jan 2021 14:28:14
	(b) (4)	



**US3312130**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:44:45
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '14:30'	(b) (4)	15 Jan 2021 14:28:14
	Karol Moore (b) (4)	
	(b) (4)	

**US3312130**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:01
User entered '14 Jan 2021 14:30'	System	15 Jan 2021 14:28:14

US3312130

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:40

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:44:45
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	15 Jan 2021 14:28:14
DataPoint set to visible.	(b) (4) System	15 Jan 2021 14:27:34

US3312130

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:40

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:44:45
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	15 Jan 2021 14:28:14
DataPoint set to visible.	(b) (4) System	15 Jan 2021 14:27:34

US3312130

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:40

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:44:45
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '98.9' F	(b) (4)	
	Karol Moore (b) (4)	15 Jan 2021 14:28:14
	(b) (4)	

**US3312130**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:44:45
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Oral (Oral)'	(b) (4)	
	Karol Moore (b) (4)	15 Jan 2021 14:28:14
	(b) (4)	

**US3312130**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:44:45
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered empty.	(b) (4)	15 Jan 2021 14:28:14
	Karol Moore (b) (4)	
	(b) (4)	

**US3312130**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:44:45
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '88'	(b) (4)	
	Karol Moore (b) (4)	15 Jan 2021 14:28:14
	(b) (4)	



**US3312130**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:01
User entered 'bpm'	System	15 Jan 2021 14:28:14

US3312130

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:40

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:44:45
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '16'	(b) (4)	
	Karol Moore (b) (4)	15 Jan 2021 14:28:14
	(b) (4)	

US3312130

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:01
User entered 'breaths/min'	System	15 Jan 2021 14:28:14

US3312130

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:40

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:44:45
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '156' reason for change: Data Entry Error	(b) (4)	
	Monica Atwood (b) (4)	03 Feb 2021 17:12:48
User entered '158'	(b) (4)	
	Karol Moore (b) (4)	15 Jan 2021 14:28:14
	(b) (4)	

**US3312130**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:01
User entered 'mmHg'	System	15 Jan 2021 14:28:14



**US3312130**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:01
User entered 'mmHg'	System	15 Jan 2021 14:28:14

**US3312130**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:01



**US3312130**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:01

US3312130

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:58:40

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:44:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Yes (Y)'	(b) (4)	15 Jan 2021 14:30:31
	Karol Moore (b) (4)	
	(b) (4)	

US3312130

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:58:40

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:44:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '14 Jan 2021'	(b) (4)	
	Karol Moore (b) (4)	15 Jan 2021 14:30:31
	(b) (4)	

US3312130

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 16:58:40

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:45:26
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Yes (Y)'	(b) (4)	
	Karol Moore (b) (4)	15 Jan 2021 14:31:39
	(b) (4)	

US3312130

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 16:58:40

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:45:26
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Query 'Per Lab Recon: SARS-COV2: Sample dated 14 JAN 2021, is still missing in PPD GCL records. Please review if the sample has been shipped, if yes, then please provide the Accession number, Tracking number, shipping date in response, as this helps to track the sample with the details provided. Please also confirm if the site had scan in barcodes through Preclarus, so that the data reflects in PPD GCL records. Thank you.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:55:28
User opened query 'Per Lab Recon: SARS-COV2: Sample dated 14 JAN 2021, is still missing in PPD GCL records. Please review if the sample has been shipped, if yes, then please provide the Accession number, Tracking number, shipping date in response, as this helps to track the sample with the details provided. Please also confirm if the site had scan in barcodes through Preclarus, so that the data reflects in PPD GCL records. Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 10:25:45
User entered '14 Jan 2021'	Karol Moore (b) (4) (b) (4)	15 Jan 2021 14:31:39

**US3312130**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:40**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:28:20
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Yes (Y)'	(b) (4)	
	Karol Moore (b) (4)	23 Feb 2021 15:41:37
	(b) (4)	

**US3312130**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:40**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:32:48
Query 'Source documents 05Mar2021. ' canceled (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 17:32:45
User opened query 'Source documents 05Mar2021. ' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 17:28:16
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '05 Feb 2021'	(b) (4)	
	Karol Moore (b) (4)	23 Feb 2021 15:41:37
	(b) (4)	

**US3312130**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:40**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:28:37
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Clinic (Clinic)'	Karol Moore (b) (4)	23 Feb 2021 15:41:37



**US3312130**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:40**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
User entered 'UNBLND_DECIDE'	System	23 Feb 2021 15:41:37

**US3312130**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:58:40**

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:35:19
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '05 Feb 2021'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Feb 2021 15:47:51

**US3312130**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:58:40**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:00:07

**US3312130**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:58:40**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:35:19
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Yes (Y)'	(b) (4)	
	Karol Moore (b) (4)	23 Feb 2021 15:47:51
	(b) (4)	

**US3312130**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:58:40**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
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 13:00:07

**US3312130**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:58:40**

**Date of unblinding (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:35:19
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '05 Feb 2021'	(b) (4)	
	Karol Moore (b) (4)	23 Feb 2021 15:47:51
	(b) (4)	

**US3312130**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:58:40**

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:35:19
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Placebo (Placebo)'	(b) (4)	
	Karol Moore (b) (4)	23 Feb 2021 15:47:51
	(b) (4)	

**US3312130**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:58:40**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:35:19
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Placebo (Placebo)'	Karol Moore (b) (4)	23 Feb 2021 15:47:51



**US3312130**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:58:40**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:35:19
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Placebo (Placebo)'	Karol Moore (b) (4)	23 Feb 2021 15:47:51

**US3312130**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:58:40**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:35:19
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Yes (Y)'	(b) (4)	
	Karol Moore (b) (4)	23 Feb 2021 15:47:51
	(b) (4)	

**US3312130**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:58:40**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
User entered '1'	System	23 Feb 2021 15:47:51

**US3312130**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:58:40**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
User entered 'I'	System	23 Feb 2021 15:47:51

US3312130

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:58:40

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	12 Mar 2021 00:24:29

US3312130

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:58:40

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	12 Mar 2021 00:24:29

**US3312130**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 16:58:40**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
User entered empty.	System	12 Mar 2021 00:24:29
DataPoint set to visible.	System	23 Feb 2021 15:47:51

US3312130

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:58:40

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered missing code ND - Not Done.	(b) (4)	
	Karol Moore (b) (4)	12 Mar 2021 00:24:29
	(b) (4)	



US3312130

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:58:40

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	12 Mar 2021 00:24:29

**US3312130**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 16:58:40**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
User entered empty.	System	12 Mar 2021 00:24:29
DataPoint set to visible.	System	23 Feb 2021 15:47:51

US3312130

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:40

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
User accepted default value 'Pre-Dose (PREDOSE)'	Karol Moore (b) (4) (b) (4)	12 Mar 2021 00:24:29

**US3312130**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Yes (Y)'	(b) (4)	
	Karol Moore (b) (4)	12 Mar 2021 00:24:29
	(b) (4)	

**US3312130**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '05 Mar 2021'	(b) (4)	
	Karol Moore (b) (4)	12 Mar 2021 00:24:29
	(b) (4)	

**US3312130**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '14:34'	(b) (4)	
	Karol Moore (b) (4)	12 Mar 2021 00:24:29
	(b) (4)	

**US3312130**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
User entered '05 Mar 2021 14:34'	System	12 Mar 2021 00:24:29

US3312130

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:40

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '98.2' F	(b) (4)	
	Karol Moore (b) (4)	12 Mar 2021 00:24:29
	(b) (4)	



**US3312130**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Oral (Oral)'	(b) (4)	
	Karol Moore (b) (4)	12 Mar 2021 00:24:29
	(b) (4)	

**US3312130**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:58:40**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered empty.	(b) (4)	
	Karol Moore (b) (4)	12 Mar 2021 00:24:29
	(b) (4)	

**US3312130**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '67'	(b) (4)	
	Karol Moore (b) (4)	12 Mar 2021 00:24:29
	(b) (4)	

**US3312130**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
User entered 'bpm'	System	12 Mar 2021 00:24:29

**US3312130**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '16'	(b) (4) Karol Moore (b) (4) (b) (4)	12 Mar 2021 00:24:29

US3312130

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
User entered 'breaths/min'	System	12 Mar 2021 00:24:29

**US3312130**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '143'	(b) (4)	
	Karol Moore (b) (4)	12 Mar 2021 00:24:29
	(b) (4)	

**US3312130**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
User entered 'mmHg'	System	12 Mar 2021 00:24:29



**US3312130**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '98'	(b) (4) Karol Moore (b) (4) (b) (4)	12 Mar 2021 00:24:29

**US3312130**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
User entered 'mmHg'	System	12 Mar 2021 00:24:29

US3312130

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:58:40

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	12 Mar 2021 00:24:29

**US3312130**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 16:58:40**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	12 Mar 2021 00:24:29

**US3312130**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 16:58:40**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
User entered empty.	System	12 Mar 2021 00:24:29
DataPoint set to visible.	System	23 Feb 2021 15:47:51

US3312130

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:40

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
User accepted default value 'Post-Dose (POSTDOSE)'	Karol Moore (b) (4) (b) (4)	12 Mar 2021 00:24:29

**US3312130**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Yes (Y)'	Karol Moore (b) (4)	12 Mar 2021 00:24:29

**US3312130**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '05 Mar 2021'	(b) (4) Karol Moore (b) (4) (b) (4)	12 Mar 2021 00:24:29



**US3312130**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '16:00'	(b) (4)	
	Karol Moore (b) (4)	12 Mar 2021 00:24:29
	(b) (4)	

**US3312130**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
User entered '05 Mar 2021 16:00'	System	12 Mar 2021 00:24:29

US3312130

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:40

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '98.1' F	(b) (4)	
	Karol Moore (b) (4)	12 Mar 2021 00:24:29
	(b) (4)	

**US3312130**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	12 Mar 2021 00:24:29

**US3312130**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:58:40**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered empty.	(b) (4)	12 Mar 2021 00:24:29
	Karol Moore (b) (4)	
	(b) (4)	

**US3312130**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '70'	(b) (4)	
	Karol Moore (b) (4)	12 Mar 2021 00:24:29
	(b) (4)	

**US3312130**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
User entered 'bpm'	System	12 Mar 2021 00:24:29

**US3312130**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '16'	(b) (4)	
	Karol Moore (b) (4)	12 Mar 2021 00:24:29
	(b) (4)	



US3312130

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
User entered 'breaths/min'	System	12 Mar 2021 00:24:29

US3312130

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:40

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '148'	(b) (4)	
	Karol Moore (b) (4)	12 Mar 2021 00:24:29
	(b) (4)	

**US3312130**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
User entered 'mmHg'	System	12 Mar 2021 00:24:29

US3312130

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:40

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '92'	(b) (4) Karol Moore (b) (4) (b) (4)	12 Mar 2021 00:24:29

**US3312130**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
User entered 'mmHg'	System	12 Mar 2021 00:24:29

**US3312130**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 16:58:40**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:41:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Yes (Y)'	Karol Moore (b) (4)	12 Mar 2021 00:24:59

**US3312130**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 16:58:40**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:41:35
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '05 Mar 2021'	(b) (4)	
	Karol Moore (b) (4)	12 Mar 2021 00:24:59
	(b) (4)	

**US3312130**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 16:58:40**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:42:39
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	12 Mar 2021 00:25:40



**US3312130**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 16:58:40**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:42:39
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered empty.	(b) (4)	12 Mar 2021 00:25:40
	Karol Moore (b) (4)	
	(b) (4)	

US3312130

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:58:40

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:42:39
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered empty.	(b) (4)	
	Karol Moore (b) (4)	12 Mar 2021 00:25:40
	(b) (4)	

**US3312130**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 16:58:40**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
User entered 'mRNA-1273'	System	12 Mar 2021 00:25:40
DataPoint set to visible.	System	23 Feb 2021 15:47:51

US3312130

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:58:40

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:42:39
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '05 Mar 2021'	(b) (4)	
	Karol Moore (b) (4)	12 Mar 2021 00:25:40
	(b) (4)	

**US3312130**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 16:58:40**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:42:39
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '15:29'	(b) (4) Karol Moore (b) (4) (b) (4)	12 Mar 2021 00:25:40

**US3312130**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 16:58:40**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
User entered '05 Mar 2021 15:29'	System	12 Mar 2021 00:25:40

US3312130

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:58:40

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:42:39
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Right Arm (RIGHT ARM)'	Karol Moore (b) (4)	12 Mar 2021 00:25:40

**US3312130**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 16:58:40**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:42:39
User entered 'ONCE'	System	12 Mar 2021 00:25:40



**US3312130**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 16:58:40**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
User entered 'INTRAMUSCULAR'	System	12 Mar 2021 00:25:40

US3312130

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:58:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:43:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Yes (Y)'	Karol Moore (b) (4)	23 Feb 2021 15:48:19

**US3312130**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:58:40**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:43:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '05 Feb 2021'	(b) (4)	
	Karol Moore (b) (4)	23 Feb 2021 15:48:19
	(b) (4)	

**US3312130**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:58:40**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:43:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '11:38'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Feb 2021 15:48:19

**US3312130**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:58:40**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
User entered '05 Feb 2021 11:38'	System	23 Feb 2021 15:48:19

**US3312130**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 16:58:40**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:43:26
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Yes (Y)'	(b) (4)	
	Karol Moore (b) (4)	23 Feb 2021 15:49:52
	(b) (4)	

**US3312130**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 16:58:40**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:43:26
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '05 Feb 2021'	(b) (4)	
	Karol Moore (b) (4)	23 Feb 2021 15:49:52
	(b) (4)	

**US3312130**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 16:58:40**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:43:26
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '11:37'	(b) (4)	
	Karol Moore (b) (4)	23 Feb 2021 15:49:52
	(b) (4)	



**US3312130**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 16:58:40**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
User entered '05 Feb 2021 11:37'	System	23 Feb 2021 15:49:52

**US3312130**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:58:40**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:43:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Yes (Y)'	Karol Moore (b) (4)	23 Feb 2021 15:49:56

**US3312130**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:58:40**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:15:52
User entered 'I'	System	23 Feb 2021 15:49:56

**US3312130**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:40**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:47
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:30:13

**US3312130**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:40**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:47
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '12 Mar 2021'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:30:13

**US3312130**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:40**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:47
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:30:13

**US3312130**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:40**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:47
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:30:13

**US3312130**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:58:40**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:47
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:14
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:30:18



**US3312130**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:58:40**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:47
User entered 'I'	System	19 Mar 2021 16:30:18

**US3312130**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:58:40**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:47
User entered '1'	System	19 Mar 2021 16:30:18
DataPoint set to visible.	System	19 Mar 2021 16:30:18

**US3312130**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:40**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:11:40

**US3312130**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:40**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '2 Apr 2021'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:11:40

**US3312130**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:40**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:11:40

**US3312130**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:40**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD29'	System	02 Apr 2021 14:11:40

**US3312130**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	02 Apr 2021 18:35:06

**US3312130**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:35:06



**US3312130**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:58:40**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '02 Apr 2021'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:35:06

**US3312130**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:58:40**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '08:33'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:35:06

**US3312130**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '02 Apr 2021 08:33'	System	02 Apr 2021 18:35:06

**US3312130**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:58:40**

**Temperature (xxx.x)**

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '98.2' F	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:35:06

**US3312130**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:35:06

**US3312130**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:58:40**

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 18:35:06

**US3312130**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '72'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:35:06

**US3312130**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	02 Apr 2021 18:35:06



**US3312130**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '16'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:35:06

**US3312130**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	02 Apr 2021 18:35:06

**US3312130**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '138'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:35:06

**US3312130**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Apr 2021 18:35:06

**US3312130**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '89'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:35:06

**US3312130**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Apr 2021 18:35:06

**US3312130**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	02 Apr 2021 18:35:06

**US3312130**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:35:06



**US3312130**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:58:40**

**Date of assessment (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '02 Apr 2021'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:35:06

**US3312130**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:58:40**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '09:39'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:35:06

**US3312130**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '02 Apr 2021 09:39'	System	02 Apr 2021 18:35:06

**US3312130**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:58:40**

**Temperature (xxx.x)**

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '98.4' F	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:35:06

**US3312130**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:35:06

**US3312130**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:58:40**

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:35:06

**US3312130**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
	(b) (4)	
User entered '75'	(b) (4), (b) (6)	02 Apr 2021 18:35:06

**US3312130**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	02 Apr 2021 18:35:06



US3312130

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:40

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '14'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:35:06

**US3312130**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	02 Apr 2021 18:35:06

**US3312130**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '132'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:35:06

**US3312130**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Apr 2021 18:35:06

**US3312130**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '86'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:35:06

**US3312130**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Apr 2021 18:35:06

**US3312130**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 16:58:40**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:35:21

**US3312130**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 16:58:40**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '02 Apr 2021'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:35:21



**US3312130**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 16:58:40**

[Was study treatment given?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:11:59

**US3312130**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 16:58:40**

[If No, reason not given](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:11:59

**US3312130**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 16:58:40**

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:11:59

**US3312130**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 16:58:40**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
User entered 'mRNA-1273'	System	02 Apr 2021 14:11:59
DataPoint set to visible.	System	19 Mar 2021 16:30:18

**US3312130**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 16:58:40**

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '2 Apr 2021'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:11:59

**US3312130**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 16:58:40**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '09:08'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:11:59

**US3312130**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 16:58:40**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '2 Apr 2021 09:08'	System	02 Apr 2021 14:11:59

US3312130

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:58:40

Which arm was used to give treatment?

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User closed query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	(b) (4)	02 Apr 2021 14:12:03
Query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' answered by data change (Site from System).	System	02 Apr 2021 14:12:03
User entered 'Right Arm (RIGHT ARM)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Apr 2021 14:12:03
User opened query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	System	02 Apr 2021 14:11:59
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	02 Apr 2021 14:11:59



**US3312130**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 16:58:40**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	02 Apr 2021 14:11:59

**US3312130**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 16:58:40**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	02 Apr 2021 14:11:59

**US3312130**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:58:40**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 14:12:09

**US3312130**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:58:40**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Apr 2021 14:12:09

**US3312130**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:40**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:55:19
	(b) (4)	
User entered 'Yes (Y)'	Monica Atwood (b) (4)	14 Apr 2021 19:49:22
	(b) (4)	

**US3312130**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:40**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:55:19
	(b) (4)	
User entered '09 Apr 2021'	Monica Atwood (b) (4)	14 Apr 2021 19:49:22
	(b) (4)	

**US3312130**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:40**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:55:19
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Monica Atwood (b) (4)	14 Apr 2021 19:49:22
	(b) (4)	

**US3312130**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:58:40**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:55:19
	(b) (4)	
User entered empty.	Monica Atwood (b) (4)	14 Apr 2021 19:49:22
	(b) (4)	



**US3312130**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:58:40**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:55:19
	(b) (4)	
User entered 'Yes (Y)'	Monica Atwood (b) (4)	14 Apr 2021 19:49:36
	(b) (4)	

**US3312130**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:58:40**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Apr 2021 19:49:36

**US3312130**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:40**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	29 Apr 2021 15:36:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 12:57:14

**US3312130**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:40**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	29 Apr 2021 15:36:55
User entered '27 Apr 2021'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 12:57:14

**US3312130**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:40**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	29 Apr 2021 15:36:55
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 12:57:14

**US3312130**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:58:40**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	29 Apr 2021 12:57:14

**US3312130**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	29 Apr 2021 15:36:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 12:57:30

**US3312130**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	29 Apr 2021 15:36:55
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 12:57:30



**US3312130**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	29 Apr 2021 15:36:55
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 12:57:30

**US3312130**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 12:57:30

**US3312130**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	29 Apr 2021 15:36:55
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 12:57:30

**US3312130**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	29 Apr 2021 15:36:55
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 12:57:30

**US3312130**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	29 Apr 2021 15:36:55
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 12:57:30

**US3312130**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	29 Apr 2021 15:36:55
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 12:57:30

**US3312130**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 12:57:30

**US3312130**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	29 Apr 2021 15:36:55
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 12:57:30



**US3312130**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 12:57:30

**US3312130**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	29 Apr 2021 15:36:55
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 12:57:30

**US3312130**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 12:57:30

**US3312130**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	29 Apr 2021 15:36:55
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 12:57:30

**US3312130**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 12:57:30

**US3312130**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 16:58:40**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	29 Apr 2021 15:36:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 12:57:55

**US3312130**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 16:58:40**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	29 Apr 2021 15:36:55
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 12:57:55

**US3312130**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:58:40**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	29 Apr 2021 15:36:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 12:58:25



**US3312130**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:58:40**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	29 Apr 2021 15:36:55
User entered '27 Apr 2021'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 12:58:25

**US3312130**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:58:40**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	29 Apr 2021 15:36:55
User entered '11:32'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 12:58:25

**US3312130**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:58:40**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '27 Apr 2021 11:32'	System	29 Apr 2021 12:58:25

**US3312130**

**Folder: Unscheduled 15 Sep 2020**

**Form: Unscheduled Visit Assessment**

**Generated On: 09 Jun 2021 16:58:40**

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:22:02
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:51
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '15 Sep 2020'	(b) (4)	
	Karol Moore (b) (4)	08 Oct 2020 14:45:13
	(b) (4)	

**US3312130**

**Folder: Unscheduled 15 Sep 2020**

**Form: Unscheduled Visit Assessment**

**Generated On: 09 Jun 2021 16:58:40**

[Physical Exam](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:22:02
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:51
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '0'	Karol Moore (b) (4)	08 Oct 2020 14:45:13

**US3312130**

**Folder: Unscheduled 15 Sep 2020**

**Form: Unscheduled Visit Assessment**

**Generated On: 09 Jun 2021 16:58:40**

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:22:02
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:51
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'l'	Karol Moore (b) (4)	08 Oct 2020 14:45:13

**US3312130**

**Folder: Unscheduled 15 Sep 2020**

**Form: Unscheduled Visit Assessment**

**Generated On: 09 Jun 2021 16:58:40**

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:22:02
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:51
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	08 Oct 2020 14:45:13

**US3312130**

**Folder: Unscheduled 15 Sep 2020**

**Form: Unscheduled Visit Assessment**

**Generated On: 09 Jun 2021 16:58:40**

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:22:02
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:07:51
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '0'	Karol Moore (b) (4)	08 Oct 2020 14:45:13



**US3312130**

**Folder: Unscheduled 15 Sep 2020**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:22:07
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:08:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Yes (Y)'	(b) (4)	
	Karol Moore (b) (4)	08 Oct 2020 14:45:49
	(b) (4)	

**US3312130**

**Folder: Unscheduled 15 Sep 2020**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:22:07
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:08:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '15 Sep 2020'	(b) (4)	
	Karol Moore (b) (4)	08 Oct 2020 14:45:49
	(b) (4)	

**US3312130**

**Folder: Unscheduled 15 Sep 2020**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:22:07
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:08:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '13:55'	(b) (4)	
	Karol Moore (b) (4)	08 Oct 2020 14:45:49
	(b) (4)	

**US3312130**

**Folder: Unscheduled 15 Sep 2020**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:22:07
User entered '15 Sep 2020 13:55'	System	08 Oct 2020 14:45:49

**US3312130**

**Folder: Unscheduled 15 Sep 2020**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:22:07
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:08:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '98.2' F	(b) (4)	
	Karol Moore (b) (4)	08 Oct 2020 14:45:49
	(b) (4)	

**US3312130**

**Folder: Unscheduled 15 Sep 2020**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:22:07
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:08:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Oral (Oral)'	(b) (4)	
	Karol Moore (b) (4)	08 Oct 2020 14:45:49
	(b) (4)	

**US3312130**

**Folder: Unscheduled 15 Sep 2020**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:22:07
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:08:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered empty.	(b) (4)	08 Oct 2020 14:45:49
	Karol Moore (b) (4)	
	(b) (4)	

**US3312130**

**Folder: Unscheduled 15 Sep 2020**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:22:07
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:08:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '70'	Karol Moore (b) (4)	08 Oct 2020 14:45:49



**US3312130**

**Folder: Unscheduled 15 Sep 2020**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:22:07
User entered 'bpm'	System	08 Oct 2020 14:45:49

**US3312130**

**Folder: Unscheduled 15 Sep 2020**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:22:07
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:08:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '16'	(b) (4)	
	Karol Moore (b) (4)	08 Oct 2020 14:45:49
	(b) (4)	

**US3312130**

**Folder: Unscheduled 15 Sep 2020**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:22:07
User entered 'breaths/min'	System	08 Oct 2020 14:45:49

**US3312130**

**Folder: Unscheduled 15 Sep 2020**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:22:07
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:08:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '172'	(b) (4)	
	Karol Moore (b) (4)	08 Oct 2020 14:45:49
	(b) (4)	

**US3312130**

**Folder: Unscheduled 15 Sep 2020**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:22:07
User entered 'mmHg'	System	08 Oct 2020 14:45:49

US3312130

Folder: Unscheduled 15 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:22:07
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:08:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	09 Oct 2020 06:47:11
User closed query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	09 Oct 2020 06:47:10
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'ncs. see Day 29 visit delayed 18sep2020' (Site from System).	Karol Moore (b) (4) (b) (4)	08 Oct 2020 14:48:41
Query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'ncs. see Day 29 visit delayed 18sep2020' (Site from System).	Karol Moore (b) (4) (b) (4)	08 Oct 2020 14:48:36
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		08 Oct 2020 14:45:49
User opened query 'Diastolic Blood Pressure reported System is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		08 Oct 2020 14:45:49
User entered '122'	Karol Moore (b) (4) (b) (4)	08 Oct 2020 14:45:49

**US3312130**

**Folder: Unscheduled 15 Sep 2020**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:22:07
User entered 'mmHg'	System	08 Oct 2020 14:45:49

**US3312130**

**Folder: Unscheduled 15 Sep 2020**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:22:07



**US3312130**

**Folder: Unscheduled 15 Sep 2020**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:58:40**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:22:07

US3312130

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:58:40

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:25:47
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:43:15
User closed query 'Per DM CLR: Per Safety Follow Up Diary Day 159, 'Experienced any new COVID-19 symptoms since last questionnaire or study contact?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = Yes, however, please note that there is no corresponding AE for this recorded data within this timeframe. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 06:28:55
Query 'Per DM CLR: Per Safety Follow Up Diary Day 159, 'Experienced any new COVID-19 symptoms since last questionnaire or study contact?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = Yes, however, please note that there is no corresponding AE for this recorded data within this timeframe. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' answered with 'PER PI, SYMPTOMS OF SAME POSITIVE COVID EVENT, NO NEW AE ' (Site from DM).	Monica Atwood (b) (4) (b) (4)	09 Apr 2021 16:36:21
User opened query 'Per DM CLR: Per Safety Follow Up Diary Day 159, 'Experienced any new COVID-19 symptoms since last questionnaire or study contact?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = Yes, however, please note that there is no corresponding AE for this recorded data within this timeframe. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 15:05:14
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:47:21
User entered 'Yes (Y)'	Monica Atwood (b) (4) (b) (4)	11 Nov 2020 16:59:56

US3312130

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:58:40

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User closed query 'Per DM CLR: Please confirm if this AE is a worsening of the same condition noted in the MH eCRF. If yes, please update the AE term to reflect the term 'worsening or exacerbation' and ensure any Con Med indications are updated if required. Otherwise, If this is a duplicate please confirm if it meets the AE reporting criteria. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Nov 2020 05:35:18
Query 'Per DM CLR: Please confirm if this AE is a worsening of the same condition noted in the MH eCRF. If yes, please update the AE term to reflect the term 'worsening or exacerbation' and ensure any Con Med indications are updated if required. Otherwise, If this is a duplicate please confirm if it meets the AE reporting criteria. ' answered with 'NA. NOT WORSENING. ONLY MADE AN AE DUE TO PROTOCOL GRADE 3' (Site from DM).	Karol Moore (b) (4) (b) (4)	24 Nov 2020 19:31:17
User opened query 'Per DM CLR: Please confirm if this AE is a worsening of the same condition noted in the MH eCRF. If yes, please update the AE term to reflect the term 'worsening or exacerbation' and ensure any Con Med indications are updated if required. Otherwise, If this is a duplicate please confirm if it meets the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 04:36:46
User coded data point as SOC: Investigations, HLGT: Cardiac and vascular investigations (excl enzyme tests), HLT: Vascular tests NEC (incl blood pressure), PT: Blood pressure systolic increased, LLT: Blood pressure systolic increased - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 17:01:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 17:01:34

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EAB) (1725)

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**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Adverse event](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	11 Nov 2020 17:01:01
User entered 'ELEVATED SYSTOLIC BLOOD PRESSURE'	Monica Atwood (b) (4)	11 Nov 2020 17:00:53
	(b) (4)	

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'No (N)'	Monica Atwood (b) (4)	11 Nov 2020 17:00:53

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'No (N)'	Monica Atwood (b) (4)	11 Nov 2020 17:00:53

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'No (N)'	Monica Atwood (b) (4)	11 Nov 2020 17:00:53

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '16 Oct 2020'	(b) (4) Monica Atwood (b) (4) (b) (4)	11 Nov 2020 17:00:53



**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered empty.	Monica Atwood (b) (4)	11 Nov 2020 17:00:53

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:58:40**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 17:00:53

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'Yes (Y)'	Monica Atwood (b) (4)	11 Nov 2020 17:00:53

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:58:40**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered empty.	Monica Atwood (b) (4)	11 Nov 2020 17:00:53

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:58:40**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered empty.	Monica Atwood (b) (4)	11 Nov 2020 17:00:53

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:58:40**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 17:00:53

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'Grade 3/Severe (Grade 3/Severe)'	Monica Atwood (b) (4)	11 Nov 2020 17:00:53

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'No (N)'	Monica Atwood (b) (4)	11 Nov 2020 17:00:53



**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	Monica Atwood (b) (4)	11 Nov 2020 17:00:53

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	Monica Atwood (b) (4)	11 Nov 2020 17:00:53

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	Monica Atwood (b) (4)	11 Nov 2020 17:00:53

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:58:40**

**Hospital Admission Date (dd MMM yyyy)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered empty.	Monica Atwood (b) (4)	11 Nov 2020 17:00:53

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered empty.	Monica Atwood (b) (4)	11 Nov 2020 17:00:53

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered empty.	Monica Atwood (b) (4)	11 Nov 2020 17:00:53

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered empty.	Monica Atwood (b) (4)	11 Nov 2020 17:00:53

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	Monica Atwood (b) (4)	11 Nov 2020 17:00:53



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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	Monica Atwood (b) (4)	11 Nov 2020 17:00:53

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	Monica Atwood (b) (4)	11 Nov 2020 17:00:53

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'Not Related (NOT RELATED)'	(b) (4) Monica Atwood (b) (4) (b) (4)	11 Nov 2020 17:00:53

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'Not Related (NOT RELATED)'	(b) (4) Monica Atwood (b) (4) (b) (4)	11 Nov 2020 17:00:53

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Folder: Adverse Events

Form: Adverse Events (1)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
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	11 Nov 2020 17:01:13
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Monica Atwood (b) (4)	11 Nov 2020 17:01:13
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	11 Nov 2020 17:00:53
	Monica Atwood (b) (4)	11 Nov 2020 17:00:53
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'I'	Monica Atwood (b) (4)	11 Nov 2020 17:00:53

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	Monica Atwood (b) (4)	11 Nov 2020 17:00:53

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	Monica Atwood (b) (4)	11 Nov 2020 17:00:53



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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) Monica Atwood (b) (4) (b) (4)	11 Nov 2020 17:00:53

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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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)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered empty.	Monica Atwood (b) (4)	11 Nov 2020 17:00:53

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered empty.	Monica Atwood (b) (4)	11 Nov 2020 17:00:53

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	11 Nov 2020 17:00:53

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	11 Nov 2020 17:00:53

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Folder: Adverse Events

Form: Adverse Events (2)

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[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:17
User entered 'USA-US300-2020-mRNA-1273-P301000022'	System	18 Dec 2020 18:46:17
User entered 'New'	(b) (4), (b) (6)	18 Dec 2020 18:46:17

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:58:40

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:57:39
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Angina pectoris, LLT: Chest pain - cardiac - version MedDRA\23.0.	Coder Import (b) (4)	08 Apr 2021 21:43:59
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	08 Apr 2021 21:43:59
Data point term sent to Coder	System	08 Apr 2021 19:39:36
Coding entries removed.	(b) (4), (b) (6)	08 Apr 2021 19:38:58
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:38:58
User entered 'CHEST PAIN (CARDIAC RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 19:38:58
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User closed query ' PV Query: The event term 'chest pain with uncontrolled DMII and HTN' contains multiple event terms. Please consider separating them into separate events.' (Site from Safety).	(b) (4), (b) (6)	18 Feb 2021 15:50:51
User closed query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if Chest Pain is respiratory related, musculoskeletal and connective tissue related , or general pain and discomfort. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 15:20:06
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Non-cardiac chest pain, LLT: Chest pain (non-cardiac) - version MedDRA\23.0.	Coder Import (b) (4)	17 Feb 2021 14:46:01
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	17 Feb 2021 14:46:01
Data point term sent to Coder	System	17 Feb 2021 12:29:01

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Folder: Adverse Events

Form: Adverse Events (2)

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[Adverse event](#)

Audit	User	Time (GMT)
User entered 'CHEST PAIN (non-CARDIAC RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Feb 2021 12:28:42
Data point term sent to Coder	System	17 Feb 2021 12:06:59
Query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if Chest Pain is respiratory related, musculoskeletal and connective tissue related , or general pain and discomfort. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 12:06:07
Coding entries removed.	(b) (4), (b) (6)	17 Feb 2021 12:06:01
User entered 'CHEST PAIN (Cardiac related)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Feb 2021 12:06:01
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest pain, LLT: Chest pain - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Feb 2021 12:01:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Feb 2021 12:01:05
Data point term sent to Coder	System	17 Feb 2021 12:00:56
Query ' PV Query: The event term 'chest pain with uncontrolled DMII and HTN' contains multiple event terms. Please consider separating them into separate events.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	17 Feb 2021 12:00:34
Coding entries removed.	(b) (4), (b) (6)	17 Feb 2021 12:00:26
User entered 'CHEST PAIN' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Feb 2021 12:00:26
User opened query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if Chest Pain is respiratory related, musculoskeletal and connective tissue related , or general pain and discomfort. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 00:34:19



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:58:40

[Adverse event](#)

Audit	User	Time (GMT)
User opened query ' PV Query: The event term 'chest pain with uncontrolled DMII and HTN' contains multiple event terms. Please consider separating them into separate events.' (Site from Safety).	(b) (4), (b) (6)	29 Dec 2020 20:03:16
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest pain, LLT: Chest pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Dec 2020 16:29:28
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Dec 2020 16:29:28
Data point term sent to Coder	System	21 Dec 2020 22:54:52
Coding entries removed.	(b) (4), (b) (6)	21 Dec 2020 22:54:37
User entered 'chest pain with uncontrolled DMII and HTN' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Dec 2020 22:54:37
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type II diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Dec 2020 11:09:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Dec 2020 11:09:42
Data point term sent to Coder	System	17 Dec 2020 23:13:18
User entered 'diabetes mellitus II, exacerbation'	(b) (4), (b) (6)	17 Dec 2020 23:12:31

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 23:12:31

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 23:12:31

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 23:12:31

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '15 Dec 2020'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 23:12:31

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 23:12:31

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:58:40**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Dec 2020 23:12:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:58:40

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	(b) (4)	17 Feb 2021 12:07:52
User entered 'No (N)' reason for change: Data Entry Error	System	17 Feb 2021 12:07:52
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	(b) (4), (b) (6)	17 Feb 2021 12:07:31
User entered 'Yes (Y)'	System	17 Dec 2020 23:12:31



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:58:40

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	(b) (4)	17 Feb 2021 12:07:31
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	17 Feb 2021 12:07:31
User entered '18 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Feb 2021 12:07:31
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	17 Feb 2021 12:07:08
User entered empty.	(b) (4), (b) (6)	17 Dec 2020 23:12:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:58:40

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	18 Feb 2021 15:51:01
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	17 Feb 2021 12:08:00
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	22 Dec 2020 14:43:46
User entered empty.	(b) (4), (b) (6)	17 Dec 2020 23:12:31

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:58:40**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Dec 2020 23:12:31

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 23:12:31

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 23:12:31

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 23:12:31

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 23:12:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:58:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	22 Dec 2020 11:35:51
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'ongoing admission at this time' (Site from System).	(b) (4), (b) (6)	17 Dec 2020 23:13:05
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	17 Dec 2020 23:12:31
User entered '1'	(b) (4), (b) (6)	17 Dec 2020 23:12:31



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Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User closed query 'Please confirm hospital admission date of 17 Dec 2020 as emergency room visit was 16 Dec 2020.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	18 Feb 2021 15:51:10
Query 'Please confirm hospital admission date of 17 Dec 2020 as emergency room visit was 16 Dec 2020.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	17 Feb 2021 12:09:01
User entered '16 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Feb 2021 12:08:53
User opened query 'Please confirm hospital admission date of 17 Dec 2020 as emergency room visit was 16 Dec 2020.' (Site from Safety).	(b) (4), (b) (6)	29 Dec 2020 20:02:06
User entered '17 Dec 2020'	(b) (4), (b) (6)	17 Dec 2020 23:12:31

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Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:58:40

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User closed query 'PV Query: Please provide or confirm hospital discharge date when available.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	18 Feb 2021 15:51:17
Query 'PV Query: Please provide or confirm hospital discharge date when available.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	17 Feb 2021 12:09:06
User entered '18 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Feb 2021 12:07:08
User opened query 'PV Query: Please provide or confirm hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	29 Dec 2020 20:00:46
User entered empty.	(b) (4), (b) (6)	17 Dec 2020 23:12:31

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 23:12:31

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 23:12:31

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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)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 23:12:31

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 23:12:31

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 23:12:31

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 23:12:31



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 23:12:31

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 23:12:31

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:58:40**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 23:12:31

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Folder: Adverse Events

Form: Adverse Events (2)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Feb 2021 15:19:57
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'CMs updated' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 12:09:45
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 00:34:34
User entered '1'	(b) (4), (b) (6)	17 Dec 2020 23:12:31

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 23:12:31

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
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)	18 Feb 2021 15:51:24
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 'updated' (Site from Safety).	(b) (4), (b) (6)	17 Feb 2021 12:09:18
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Feb 2021 12:07:08
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)	22 Dec 2020 14:44:02
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	17 Dec 2020 23:12:31

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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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)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 23:12:31

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User closed query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	18 Feb 2021 15:51:39
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)	18 Feb 2021 15:51:35
User closed query 'Per DM CLR: SAE Narrative = PAST HISTORY OF ANGINA. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 15:19:52
User closed query 'Per DM CLR: SAE Narrative = WAS INSTRUCTED TO TAKE TYLENOL. Please confirm if this was taken; if yes, ensure that this is captured in the appropriate eCRF.	(b) (4), (b) (6)	18 Feb 2021 15:19:50
' (Site from DM).		
User closed query 'Per DM CLR: SAE Narrative = SAE OF DIABETES EXACERBATION. 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.	(b) (4), (b) (6)	18 Feb 2021 15:19:48
' (Site from DM).		
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 'Email sent with redacted Medical records 17Feb2020' (Site from Safety).	(b) (4), (b) (6)	17 Feb 2021 12:10:09

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3312130

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:58:40

[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: SAE Narrative = WAS INSTRUCTED TO TAKE TYLENOL. Please confirm if this was taken; if yes, ensure that this is captured in the appropriate eCRF.   ' answered with 'CM updated' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 12:09:53
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' answered with 'medical history updated' (Site from Safety).	(b) (4), (b) (6)	17 Feb 2021 12:09:30
Query 'Per DM CLR: SAE Narrative = PAST HISTORY OF ANGINA. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 12:06:31
Query 'Per DM CLR: SAE Narrative = SAE OF DIABETES EXACERBATION. 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 'added' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 12:06:14
User opened query 'Per DM CLR: SAE Narrative = SAE OF DIABETES EXACERBATION. 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)	11 Jan 2021 00:34:10
User opened query 'Per DM CLR: SAE Narrative = WAS INSTRUCTED TO TAKE TYLENOL. Please confirm if this was taken; if yes, ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 00:34:04
User opened query 'Per DM CLR: SAE Narrative = PAST HISTORY OF ANGINA. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 00:33:49
Query 'PV Query: Please provide or confirm hospital discharge date when available.' canceled (Site from Safety).	(b) (4), (b) (6)	29 Dec 2020 20:02:37

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3312130

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:58:40

[Narrative](#)

Audit	User	Time (GMT)
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 Dec 2020 20:02:33
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 Dec 2020 20:01:47
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' canceled (Site from Safety).	(b) (4), (b) (6)	29 Dec 2020 16:26:29
Query 'PV Query: Please provide the results of any COVID-19 testing, if available/applicable.' canceled (Site from Safety).	(b) (4), (b) (6)	29 Dec 2020 16:26:18
User opened query 'PV Query: Please provide the results of any COVID-19 testing, if available/applicable.' (Site from Safety).	(b) (4), (b) (6)	22 Dec 2020 14:44:25
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Dec 2020 14:43:33
User opened query 'PV Query: Please provide or confirm hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	22 Dec 2020 14:43:24

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:58:40

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT IS HISTORIAN.NO DOCUMENTS AT THIS TIME TO CONFIRM THE FACTS OF THIS SAE.50 YR OLD HYPERTENSIVE MALE DIABETIC, VASCULOPATH(HISTORY OF CAD, ANGIOPLASTY 2017) S/P DOSE 1 ON 08/18/20, DOSE 2 ON 09/18/20, WHO ON 12/15/20EVENING CALLED TO REPORT ONSET IN AM OF HEADACHE, SUBJECTIVE FEVER, FATIGUE, MYALGIA, DIARRHEA,SORE THROAT, LEFT OTALGIA,RHINORRHEA, DIMINISHED TASTE,CONFUSION, MILD SHORTNESS OF AIR. HE REPORTED THAT SYMPTOMS DID NOT RESEMBLE PAST HISTORY OF ANGINA. HE DENIED COUGH, WHEEZING, EMESIS,AND WAS ALERT,ORIENTED AND APPROPRIATE ON THE PHONE.SUBJECT STATED HE REPORTED CONFUSION TO MEAN THAT HE WAS UNDER A GREAT DEAL OF STRESS AND NOW WITH THESE SYMPTOMS "I'M NOT SURE WHAT TO DO." WAS INSTRUCTED TO TAKE TYLENOL AND TO CALL SITE AND VISIT ER IF NO IMPROVEMENT OR WORSENING OF SYMPTOMS, BUT OTHERWISE VISIT SITE FOR ILLNESS VISIT THE NEXT MORNING. ILLNESS VISIT AT SITE12/16/20 REPORTED SYMPTOMS PERSISTED AND HE ADDED COUGH TO LIST. WAS FOUND TO HAVE A G3 BP175/115. HISTORY OF HIGH BP WHEN UNDER DURESS AND WHEN HAVING NOT TAKEN HIS BP MEDS,WHICH WAS THE CASE AT ILLNESS VISIT.HR WAS 79, RESP 14, TEMP 98.3 (NO ANTIPYRETICS IN PRECEDING 6 HOURS), O2SAT WAS 99%.PHYSICAL EXAM WAS NORMAL INCLUDING ABSENCE OF COUGH, EXCEPT SUBJECT SEEMED TO BE UNDER DURESS AND WAS AGITATED BY DISCUSSION WITH PROVIDERS REGARDING HIS BLOOD PRESSURE AND BECAUSE HE WAS ADVISED TO NOT WORK DUE TO	(b) (4), (b) (6)	21 Dec 2020 22:55:16

US3312130

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:58:40

[Narrative](#)

Audit	User	Time (GMT)
PROBABILITY OF HAVING COVID.SUBJECT CALLED SITE12/17/20 TO REPORT THAT PREVIOUS NIGHT HE CONTINUED TO FEEL ILL WHILE AT WORK AND COULD NOT PERFORM THE HEAVY LIFTING THAT WAS BEING ASKED OF HIM, SO HE WENT TO ER.AT HOSPITAL HE WAS ADMITTED FOR UNCONTROLLED DIABETES AND HYPERTENSION WITH FINGERSTICK GLUCOSE &gt; 600 AND BP 194/105.SUBJECT IS NOT IN ICU AND REPORTS THAT HIS DOCTORS HAVE PLANS TO RELEASE HIM TOMORROW WITH NO PLANS FOR ANY SPECIAL OR INVASIVE PROCEDURES.WILL PROCURE MEDICAL RECORDS.SAE OF DIABETES EXACERBATION NOT RELATED TO IP,POSSIBLY RELATED TO COVID. Follow up continued in Source' reason for change: Data Entry Error		

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:58:40

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Subject is historian.No documents at this time to confirm the facts of this SAE.50 yr old hypertensive male diabetic, vasculopath(history of CAD, angioplasty 2017) s/p dose 1 on 08/18/20, dose 2 on 09/18/20, who on 12/15/20evening called to report onset in am of headache, subjective fever, fatigue, myalgia, diarrhea,sore throat, left otalgia,rhinorrhea, diminished taste,confusion, mild shortness of air. He reported that symptoms did not resemble past history of angina. He denied cough, wheezing, emesis,and was alert,oriented and appropriate on the phone.Subject stated he reported confusion to mean that he was under a great deal of stress and now with these symptoms "I'm not sure what to do." was instructed to take Tylenol and to call site and visit ER if no improvement or worsening of symptoms, but otherwise visit site for illness visit the next morning. Illness visit at site12/16/20 reported symptoms persisted and he added cough to list. was found to have a G3 BP175/115. history of high bp when under duress and when having not taken his bp meds,which was the case at illness visit.HR was 79, resp 14, Temp 98.3 (no antipyretics in preceding 6 hours), o2sat was 99%.Physical exam was normal including absence of cough, except subject seemed to be under duress and was agitated by discussion with providers regarding his blood pressure and because he was advised to not work due to probability of having Covid.Subject called site12/17/20 to report that previous night he continued to feel ill while at work and could not perform the heavy lifting that was being asked of him, so he went to ER.At hospital he was admitted for uncontrolled diabetes and hypertension with fingerstick glucose &gt; 600 and bp 194/105.Subject is not in icu and reports that his doctors have plans to release him tomorrow with no plans for any special or invasive procedures.Will procure medical records.SAE of diabetes exacerbation not related to IP,possibly related to Covid'	(b) (4), (b) (6)	17 Dec 2020 23:12:31

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Dec 2020 23:12:31

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Dec 2020 23:12:31

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	17 Dec 2020 23:12:31



**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:58:40**

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:16
User entered 'USA-US300-2020-mRNA-1273-P301000022'	(b) (4), (b) (6)	22 Dec 2020 19:51:11

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:58:40

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4)	22 Dec 2020 00:15:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Dec 2020 00:15:38
Data point term sent to Coder	System	22 Dec 2020 00:14:46
User entered 'symptomatic covid 19'	(b) (4), (b) (6)	22 Dec 2020 00:14:42

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:58:40**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 00:14:42

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:58:40**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 00:14:42

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:58:40**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 00:14:42

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:58:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User closed query ' PV Query: COVID-19 symptoms have been reported starting on 15 Dec 2020. Please update the event start date to reflect the date that the subject first experienced symptoms, as per the protocol.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:04:08
Query ' PV Query: COVID-19 symptoms have been reported starting on 15 Dec 2020. Please update the event start date to reflect the date that the subject first experienced symptoms, as per the protocol.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	21 Jan 2021 17:07:53
User entered '15 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Jan 2021 02:34:16
User opened query ' PV Query: COVID-19 symptoms have been reported starting on 15 Dec 2020. Please update the event start date to reflect the date that the subject first experienced symptoms, as per the protocol.' (Site from Safety).	(b) (4), (b) (6)	29 Dec 2020 20:04:27
User entered '16 Dec 2020'	(b) (4), (b) (6)	22 Dec 2020 00:14:42

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:58:40**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 00:14:42

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:58:40**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Dec 2020 00:14:42



**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:58:40**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Karol Moore (b) (4)	15 Jan 2021 14:11:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Dec 2020 00:14:42

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:58:40

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User closed query 'PV Query: The events, uncontrolled diabetes and symptomatic COVID 19, resolved on 25 Dec 2020. Please clarify what symptoms the subject was still having as the subject was discharged on 18 Dec 2020.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	11 Mar 2021 18:20:32
Query 'PV Query: The events, uncontrolled diabetes and symptomatic COVID 19, resolved on 25 Dec 2020. Please clarify what symptoms the subject was still having as the subject was discharged on 18 Dec 2020.' answered with 'see symptom log, many covid symptoms still present that did warrant hospitalization. Hospitalization was not for Covid 19 symptoms.' (Site from Safety).	(b) (4), (b) (6)	10 Mar 2021 00:24:07
User opened query 'PV Query: The events, uncontrolled diabetes and symptomatic COVID 19, resolved on 25 Dec 2020. Please clarify what symptoms the subject was still having as the subject was discharged on 18 Dec 2020.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 13:35:57
User closed query 'PV Query: Please provide the event end date (when symptoms have resolved).' (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 17:04:13
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	21 Jan 2021 17:08:16
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	21 Jan 2021 17:08:16
Query 'PV Query: Please provide the event end date (when symptoms have resolved).' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	21 Jan 2021 17:08:06

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:58:40

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	15 Jan 2021 14:11:34
User entered '25 Dec 2020' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	15 Jan 2021 14:11:34
User opened query 'PV Query: Please provide the event end date (when symptoms have resolved).' (Site from Safety).	(b) (4), (b) (6)	29 Dec 2020 20:04:45
User entered empty.	(b) (4), (b) (6)	22 Dec 2020 00:14:42

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:58:40**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 00:14:42

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:58:40**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Dec 2020 00:14:42

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:58:40**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 00:14:42

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:58:40**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 00:14:42

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:58:40**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 00:14:42



**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:58:40**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 00:14:42

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:58:40**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 00:14:42

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:58:40**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 00:14:42

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**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 00:14:42

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 00:14:42

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 00:14:42

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**Form: Adverse Events (3)**

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 00:14:42

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 00:14:42



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**Form: Adverse Events (3)**

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 00:14:42

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:58:40**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 00:14:42

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 00:14:42

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**Form: Adverse Events (3)**

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 00:14:42

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:58:40**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:09:29
User entered '1'	(b) (4), (b) (6)	22 Dec 2020 00:14:42

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Folder: Adverse Events

Form: Adverse Events (3)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:04:24
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	21 Jan 2021 17:09:36
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 17:09:29
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	29 Dec 2020 20:05:25
User entered '0'	(b) (4), (b) (6)	22 Dec 2020 00:14:42

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 00:14:42

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:58:40

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
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)	22 Jan 2021 17:04:36
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 'updated' (Site from Safety).	(b) (4), (b) (6)	21 Jan 2021 17:08:26
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 17:08:16
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 Dec 2020 20:05:56
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	22 Dec 2020 00:14:42



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**Folder: Adverse Events**

**Form: Adverse Events (3)**

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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)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 00:14:42

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Form: Adverse Events (3)

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User closed query 'Per DM CLR: SAE Narrative = HE WAS TREATED WITH NITROGLYCERIN, INSULIN. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Feb 2021 15:23:38
User closed query 'Per DM CLR: SAE Narrative = EKG AND NORMAL TROPONINS X 3. 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 Feb 2021 15:23:36
User closed query 'Per DM CLR: SAE Narrative = ECHO. 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 Feb 2021 15:23:33
User closed query 'Per DM CLR: SAE Narrative = CXR. 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 Feb 2021 15:22:09
User closed query 'Per DM CLR: SAE Narrative = MILD HYPONATREMIA AND ELEVATED CREATININE. However, please review and verify if these 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 Feb 2021 15:22:07
User closed query 'Per DM CLR: SAE Narrative = HUMULIN NR INSULIN. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 15:22:04

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Form: Adverse Events (3)

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Narrative = UNCONTROLLED DIABETES. However, please review and verify if this is a worsening of the Med History condition and should be recorded as Adverse Event. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 15:22:02
User closed query 'Per DM CLR: Narrative = GLUCOSE CONTROL AND FLUIDS. However, these were not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 15:21:58
User closed query 'Per DM CLR: Narrative = MILD DIASTOLIC DYSFUNCTION AND SEPTAL LVH. However, please review and verify if these should be recorded as a separate AE. If yes, ensure to record these medical conditions in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 15:21:56
User closed query 'Per DM CLR: Narrative = POLYSUBSTANCE ABUSE. 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 Feb 2021 15:21:54
User closed query 'Per DM CLR: Narrative = POSSIBLE STRESS TEST AS OUTPATIENT. However, please confirm if this was already performed. If yes, ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 15:21:52
Query 'Per DM CLR: Narrative = MILD DIASTOLIC DYSFUNCTION AND SEPTAL LVH. However, please review and verify if these should be recorded as a separate AE. If yes, ensure to record these medical conditions in the AE eCRF as appropriate.' answered with 'not separate AEs per PI, included in Uncontrolled HTn' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 12:31:53
Query 'Per DM CLR: Narrative = POSSIBLE STRESS TEST AS OUTPATIENT. However, please confirm if this was already performed. If yes, ensure that this is captured in the appropriate eCRF. ' answered with 'Not done' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 12:27:55

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[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Narrative = POLYSUBSTANCE ABUSE. 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 'updated history' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 12:27:46
Query 'Per DM CLR: Narrative = GLUCOSE CONTROL AND FLUIDS. However, these were not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'updated CM' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 12:27:40
Query 'Per DM CLR: Narrative = UNCONTROLLED DIABETES. However, please review and verify if this is a worsening of the Med Histroy condition and should be recorded as Adverse Event. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' answered with 'updated AE' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 12:27:04
Query 'Per DM CLR: SAE Narrative = HUMULIN NR INSULIN. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'updated CM' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 12:26:51
Query 'Per DM CLR: SAE Narrative = MILD HYPONATREMIA AND ELEVATED CREATININE. However, please review and verify if these should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' answered with 'updated to add hyponatremia' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 12:26:45
Query 'Per DM CLR: SAE Narrative = CXR. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'not a procedure-NA' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 12:26:28
Query 'Per DM CLR: SAE Narrative = ECHO. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'NA- ' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 12:26:19

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[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: SAE Narrative = EKG AND NORMAL TROPONINS X 3. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'not a procedure-NA on con procedure page' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 12:25:58
Query 'Per DM CLR: SAE Narrative = HE WAS TREATED WITH NITROGLYCERIN, INSULIN. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'CM updated' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 12:25:40
User opened query 'Per DM CLR: Narrative = POSSIBLE STRESS TEST AS OUTPATIENT. However, please confirm if this was already performed. If yes, ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 04:27:41
User opened query 'Per DM CLR: Narrative = POLYSUBSTANCE ABUSE. 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)	16 Feb 2021 04:27:27
User opened query 'Per DM CLR: Narrative = GLUCOSE CONTROL AND FLUIDS. However, these were not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 04:27:18
User opened query 'Per DM CLR: Narrative = MILD DIASTOLIC DYSFUNCTION AND SEPTAL LVH. However, please review and verify if these should be recorded as a separate AE. If yes, ensure to record these medical conditions in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 04:26:50
User opened query 'Per DM CLR: Narrative = UNCONTROLLED DIABETES. However, please review and verify if this is a worsening of the Med History condition and should be recorded as Adverse Event. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 04:26:27

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: SAE Narrative = SUBJECT PRESENTED TO ER IN PM 16DEC20 WITH COMPLAINTS OF CHEST PAIN. Please confirm if this pertains to AE #2. If yes, please verify if this is the date when CHEST PAIN started; and if so, reconcile the start date of AE #2. Update eCRF as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 07:38:51
Query 'Per DM CLR: SAE Narrative = SUBJECT PRESENTED TO ER IN PM 16DEC20 WITH COMPLAINTS OF CHEST PAIN. Please confirm if this pertains to AE #2. If yes, please verify if this is the date when CHEST PAIN started; and if so, reconcile the start date of AE #2. Update eCRF as appropriate. Otherwise, clarify. ' answered with 'not related to AE of COVID, as it was an incidental finding in ER and not initially symptomatic' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 17:20:04
User opened query 'Per DM CLR: SAE Narrative = HUMULIN NR INSULIN. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 00:36:37
User opened query 'Per DM CLR: SAE Narrative = MILD HYPONATREMIA AND ELEVATED CREATININE. However, please review and verify if these 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)	11 Jan 2021 00:36:24
User opened query 'Per DM CLR: SAE Narrative = CXR. 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)	11 Jan 2021 00:36:18
User opened query 'Per DM CLR: SAE Narrative = ECHO. 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)	11 Jan 2021 00:36:10
User opened query 'Per DM CLR: SAE Narrative = EKG AND NORMAL TROPONINS X 3. 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)	11 Jan 2021 00:36:04

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EAB) (1725)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: SAE Narrative = HE WAS TREATED WITH NITROGLYCERIN, INSULIN. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 00:35:57
User opened query 'Per DM CLR: SAE Narrative = SUBJECT PRESENTED TO ER IN PM 16DEC20 WITH COMPLAINTS OF CHEST PAIN. Please confirm if this pertains to AE #2. If yes, please verify if this is the date when CHEST PAIN started; and if so, reconcile the start date of AE #2. Update eCRF as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 00:35:50

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'Subject presented to ER in pm 16Dec20 with complaints of chest pain of tightness quality and up to 9 out of 10 intensity while lifting boxes, mild shortness of air when breathing cold air, fatigue, headache, and dizziness, without nausea, emesis, diaphoresis. He was unsure if pain was similar to angina that led to coronary stenting in 2017. ROS was otherwise negative. Physical exam normal. BP 173/106, O2sat 98% on RA, Glucose 629. Subject was admitted for chest pain with uncontrolled diabetes and hypertension. He was treated with nitroglycerin, insulin and resumption of home meds (subject agreed he was non-compliant.) MI was ruled out per NSR ekg and normal troponins x 3. Echo showed 50-55% EF with mild diastolic dysfunction and septal LVH. CXR was normal. A mild hyponatremia and elevated creatinine corrected with glucose control and fluids. Ketones were normal. Subject agreed to distant polysubstance abuse issue and UDS was negative. Covid RT-PCR was positive. After improvement in symptoms, correction of glucose to 130's and bp to 140's subject was discharged on 18Dec20 with plan of continuing with Humulin NR insulin, resumption of home meds, follow-ups with PCP and Cardiologist and possible stress test as outpatient. Subject hospitalized for chest pain with uncontrolled diabetes and hypertension due to noncompliance, NR to IP. (SEE SEPARATE SAE) Covid PCR is positive but incidental to this SAE; Covid-19 is not the cause of this hospitalization; therefore, is not an SAE in itself'	(b) (4), (b) (6)	22 Dec 2020 00:14:42



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**Form: Adverse Events (3)**

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	22 Dec 2020 00:14:42

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:58:40**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	22 Dec 2020 00:14:42

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:58:40**

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:17
User entered 'USA-US300-2020-mRNA-1273-P301000022'	(b) (4), (b) (6)	18 Feb 2021 15:47:34

US3312130

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:58:40

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User closed query 'Per DM CLR: Please verify the severity as a Worsening of the Med History condition would be expected to be > Grade of MH. Please confirm/update the severity or remove if a duplicate from baseline medical history.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 11:41:53
Query 'Per DM CLR: Please verify the severity as a Worsening of the Med History condition would be expected to be > Grade of MH. Please confirm/update the severity or remove if a duplicate from baseline medical history.' answered with 'correct, this AE is Grade 3. There is no grading on medical history so correct as entered.' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 00:25:01
User opened query 'Per DM CLR: Please verify the severity as a Worsening of the Med History condition would be expected to be > Grade of MH. Please confirm/update the severity or remove if a duplicate from baseline medical history.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 16:39:07
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Diabetes mellitus inadequate control, LLT: Type II diabetes mellitus inadequate control - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Feb 2021 16:36:00
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Feb 2021 16:36:00
Data point term sent to Coder	System	17 Feb 2021 12:02:57
User entered 'uncontrolled diabetes Mellitus II'	(b) (4), (b) (6)	17 Feb 2021 12:02:27

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:58:40**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:02:27

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:58:40**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:02:27

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:58:40**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:02:27

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '16 Dec 2020'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:02:27



**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:58:40**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:02:27

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:58:40**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Feb 2021 12:02:27

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:58:40**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:02:27

US3312130

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:58:40

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:57:39
Signature has been broken.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 19:21:12
User entered '18 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 19:21:12
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User closed query 'PV Query: The events, uncontrolled diabetes and symptomatic COVID 19, resolved on 25 Dec 2020. Please clarify what symptoms the subject was still having as the subject was discharged on 18 Dec 2020.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	11 Mar 2021 18:24:28
Query 'PV Query: The events, uncontrolled diabetes and symptomatic COVID 19, resolved on 25 Dec 2020. Please clarify what symptoms the subject was still having as the subject was discharged on 18 Dec 2020.' answered with 'hospitalization was not for COVID-19, see symptom log. These two events are not related and DC date does not affect covid symptom date.' (Site from Safety).	(b) (4), (b) (6)	10 Mar 2021 00:26:06
User opened query 'PV Query: The events, uncontrolled diabetes and symptomatic COVID 19, resolved on 25 Dec 2020. Please clarify what symptoms the subject was still having as the subject was discharged on 18 Dec 2020.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 13:35:15
User entered '25 Dec 2020'	(b) (4), (b) (6)	17 Feb 2021 12:02:27

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:58:40**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:02:27

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:58:40**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Feb 2021 12:02:27

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:58:40**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:02:27

US3312130

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:58:40

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	(b) (4)	17 Feb 2021 12:02:46
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	17 Feb 2021 12:02:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Feb 2021 12:02:27



**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:58:40**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:02:27

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:58:40**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:02:27

US3312130

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:58:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4)	17 Feb 2021 12:02:46
Query 'Requires inpatient or prolongation of existing System Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		17 Feb 2021 12:02:46
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Feb 2021 12:02:46
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	17 Feb 2021 12:02:27
User entered '0'	(b) (4), (b) (6)	17 Feb 2021 12:02:27

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:58:40**

**Hospital Admission Date (dd MMM yyyy)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '16 Dec 2020'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:02:27

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:58:40**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '18 Dec 2020'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:02:27

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:58:40**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:02:27

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:58:40**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:02:27

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:58:40**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:02:27



**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:58:40**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:02:27

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:58:40**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:02:27

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:58:40**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:02:27

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:58:40**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:02:27

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:58:40**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	17 Feb 2021 12:04:59
reason for change: Data Entry Error	(b) (4), (b) (6)	
User entered 'None (NONE)'	(b) (4), (b) (6)	17 Feb 2021 12:02:27

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:58:40**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:02:27

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:58:40**

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'I'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:02:27

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:58:40**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:02:27



**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:58:40**

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:02:27

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:58:40**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:02:27

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:58:40**

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'See SAE # 2 (split per query)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:02:27

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:58:40**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Feb 2021 12:02:27

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:58:40**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Feb 2021 12:02:27

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:58:40**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	17 Feb 2021 12:02:27

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:58:40**

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:17
User entered 'USA-US300-2020-mRNA-1273-P301000022'	(b) (4), (b) (6)	18 Feb 2021 15:47:52

US3312130

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:58:40

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User closed query 'Per DM CLR: Please verify the severity as a Worsening of the Med History condition would be expected to be > Grade of MH. Please confirm/update the severity or remove if a duplicate from baseline medical history.' (Site from DM). Query 'Per DM CLR: Please verify the severity as a Worsening of the Med History condition would be expected to be > Grade of MH. Please confirm/update the severity or remove if a duplicate from baseline medical history.' answered with 'severity is correct, grade 4 is not applicable for this AE' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Mar 2021 13:40:46
User opened query 'Per DM CLR: Please verify the severity as a Worsening of the Med History condition would be expected to be > Grade of MH. Please confirm/update the severity or remove if a duplicate from baseline medical history.' (Site from DM).	(b) (4), (b) (6)	06 Mar 2021 19:11:20
User opened query 'Per DM CLR: Please verify the severity as a Worsening of the Med History condition would be expected to be > Grade of MH. Please confirm/update the severity or remove if a duplicate from baseline medical history.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 16:39:35
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Uncontrolled hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Feb 2021 12:05:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Feb 2021 12:05:05
Data point term sent to Coder	System	17 Feb 2021 12:04:58
User entered 'uncontrolled Hypertension'	(b) (4), (b) (6)	17 Feb 2021 12:04:04



**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:58:40**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:04:04

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:58:40**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:04:04

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:58:40**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:04:04

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '16 Dec 2020'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:04:04

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:58:40**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:04:04

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:58:40**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Feb 2021 12:04:04

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:58:40**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:04:04

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:58:40**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '18 Dec 2020'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:04:04



**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:58:40**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:04:04

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:58:40**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Feb 2021 12:04:04

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:58:40**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:04:04

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:58:40**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:04:04

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:58:40**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:04:04

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:58:40**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:04:04

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:58:40**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'I'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:04:04

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:58:40**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '16 Dec 2020'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:04:04



**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:58:40**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '18 Dec 2020'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:04:04

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:58:40**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:04:04

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:58:40**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:04:04

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:58:40**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:04:04

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:58:40**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:04:04

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:58:40**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:04:04

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:58:40**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:04:04

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:58:40**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:04:04



**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:58:40**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	17 Feb 2021 12:04:41
reason for change: Data Entry Error	(b) (4), (b) (6)	
User entered 'None (NONE)'	(b) (4), (b) (6)	17 Feb 2021 12:04:04

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:58:40**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:04:04

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:58:40**

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'I'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:04:04

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:58:40**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:04:04

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:58:40**

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:04:04

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:58:40**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:04:04

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:58:40**

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'See SAE narrative AE #2 (Split per query)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:04:04

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:58:40**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Feb 2021 12:04:04



**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:58:40**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Feb 2021 12:04:04

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:58:40**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	17 Feb 2021 12:04:04

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:58:40**

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:17
User entered 'USA-US300-2021-mRNA-1273-P301000015'	System	18 Feb 2021 17:55:13
User entered 'New'	(b) (4), (b) (6)	18 Feb 2021 17:55:13

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:58:40

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User coded data point as SOC: Cardiac disorders, HLT: Ischaemic coronary artery disorders, PT: Angina pectoris, LLT: Angina pectoris - version MedDRA\\23.0.	Coder Import (b) (4)	17 Feb 2021 19:26:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Feb 2021 19:26:02
Data point term sent to Coder	System	17 Feb 2021 19:24:52
User entered 'angina'	(b) (4), (b) (6)	17 Feb 2021 19:24:34

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:58:40**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:24:34

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:58:40**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:24:34

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:58:40**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:24:34

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:58:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '10 Feb 2021' reason for change: Data Entry Error	(b) (4)	11 Mar 2021 00:17:56
User entered '11 Feb 2021'	(b) (4), (b) (6)	17 Feb 2021 19:24:34



**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:58:40**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:24:34

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:58:40**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Feb 2021 19:24:34

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:58:40**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:24:34

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:58:40**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '13 Feb 2021'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:24:34

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:58:40**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:24:34

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:58:40**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Feb 2021 19:24:34

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:58:40**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:24:34

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Folder: Adverse Events

Form: Adverse Events (6)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:24:34



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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:58:40**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:24:34

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:58:40**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:24:34

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:58:40**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'I'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:24:34

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:58:40**

**Hospital Admission Date (dd MMM yyyy)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '11 Feb 2021'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:24:34

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:58:40**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '13 Feb 2021'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:24:34

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:58:40**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:24:34

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:24:34

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:58:40**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:24:34



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**Folder: Adverse Events**

**Form: Adverse Events (6)**

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:24:34

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:24:34

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:58:40**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:24:34

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:58:40**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:24:34

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Form: Adverse Events (6)

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Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User closed query 'PV Query: As the last dose of study drug was given on 18 Sep 2020, please update the action taken with study drug from none to not applicable' (Site from Safety).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 14:48:45
Query 'PV Query: As the last dose of study drug was given on 18 Sep 2020, please update the action taken with study drug from none to not applicable' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	06 Mar 2021 19:11:50
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Mar 2021 19:11:43
User opened query 'PV Query: As the last dose of study drug was given on 18 Sep 2020, please update the action taken with study drug from none to not applicable' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 14:36:17
User entered 'None (NONE)'	(b) (4), (b) (6)	17 Feb 2021 19:24:34

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Form: Adverse Events (6)

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None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	17 Feb 2021 19:25:25
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	17 Feb 2021 19:24:34
User entered '0'	(b) (4), (b) (6)	17 Feb 2021 19:24:34

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Form: Adverse Events (6)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '1' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:25:25
User entered '0'	(b) (4), (b) (6)	17 Feb 2021 19:24:34

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:58:40

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:18:30
Signature has been broken.	(b) (4)	
	Karol Moore (b) (4)	18 Mar 2021 15:39:09
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Karol Moore (b) (4)	18 Mar 2021 15:39:09
	(b) (4)	
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	17 Feb 2021 19:24:34



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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	17 Feb 2021 19:24:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Feb 2021 19:24:50
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4), (b) (6)	17 Feb 2021 19:24:50
Data Entry Error		
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Feb 2021 19:24:34
User entered empty.	(b) (4), (b) (6)	17 Feb 2021 19:24:34

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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)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:24:34

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User closed query 'Per DM CLR: Narrative = CXR. 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)	29 Mar 2021 11:10:26
User closed query 'Per DM CLR: Narrative = CARDIAC PET STRESS (2/12/21). 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)	29 Mar 2021 11:10:23
User closed query 'Per DM CLR: Narrative = TROPONIN. However, this is not recorded in the ConProc eCRF (i.e., Blood work). Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 11:10:21
User closed query 'Per DM CLR: Narrative = EKG. 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)	29 Mar 2021 11:10:15
User closed query 'Per DM CLR: Narrative = STENT X2 TO LAD IN 2017. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 11:10:09
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	26 Mar 2021 18:42:37
Query 'Per DM CLR: Narrative = STENT X2 TO LAD IN 2017. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' answered with 'updated medical history' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 19:47:57

US3312130

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:58:40

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'PREVIOUS ANSWERED-SEE QUERY RESPONSE :no covid test documented in medical records for this hospital admission' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 19:45:37
Query 'Per DM CLR: Narrative = CXR. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Diagnostic, not procedure: does not need recorded on procedure page' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 19:37:00
Query 'Per DM CLR: Narrative = CARDIAC PET STRESS (2/12/21). However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Diagnostic, not procedure: does not need recorded on procedure page' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 19:36:56
Query 'Per DM CLR: Narrative = TROPONIN. However, this is not recorded in the ConProc eCRF (i.e., Blood work). Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Diagnostic blood test is not procedure: does not need recorded on procedure page' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 19:33:39
Query 'Per DM CLR: Narrative = EKG. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Diagnostic, not procedure: does not need recorded on procedure page' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 19:33:21
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 11:57:20
User opened query 'Per DM CLR: Narrative = CARDIAC PET STRESS (2/12/21). 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)	24 Mar 2021 02:56:33

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:58:40

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Narrative = CXR. 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)	24 Mar 2021 02:56:27
User opened query 'Per DM CLR: Narrative = TROPONIN. However, this is not recorded in the ConProc eCRF (i.e., Blood work). Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 02:56:22
User opened query 'Per DM CLR: Narrative = EKG. 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)	24 Mar 2021 02:56:16
User opened query 'Per DM CLR: Narrative = STENT X2 TO LAD IN 2017. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 02:56:11
User closed query 'PV Query: Please confirm if subject received mRNA-1273 after being unblinded on 05 Feb 2021. If yes, please update eCRF accordingly.' (Site from Safety).	(b) (4), (b) (6)	18 Mar 2021 14:22:05
User closed query 'PV Query: Please provide dates for PET, EKG, troponin results, and chest x-ray.' (Site from Safety).	(b) (4), (b) (6)	18 Mar 2021 14:22:03
Query 'PV Query: Please provide dates for PET, EKG, troponin results, and chest x-ray.' answered with 'EKG, Troponin, CXR done 11/Feb/2021 PET scan done 12Feb2021' (Site from Safety).	(b) (4), (b) (6)	17 Mar 2021 20:45:21
Query 'PV Query: Please confirm if subject received mRNA-1273 after being unblinded on 05 Feb 2021. If yes, please update eCRF accordingly.' answered with 'Not given at Decision visit 05Feb2021/ Subject returned for Day 1 visit and dosed 05Mar2021' (Site from Safety).	(b) (4), (b) (6)	17 Mar 2021 19:49:14
User opened query 'PV Query: Please provide dates for PET, EKG, troponin results, and chest x-ray.' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 12:31:19

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:58:40

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please confirm if subject received mRNA-1273 after being unblinded on 05 Feb 2021. If yes, please update eCRF accordingly.' (Site from Safety). User signature succeeded.	(b) (4), (b) (6) [REDACTED]	15 Mar 2021 12:31:12
	Carlos Fierro (b) (4) [REDACTED]	12 Mar 2021 15:47:21
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response' (Site from Safety).	(b) (4) (b) (4), (b) (6) [REDACTED]	10 Mar 2021 14:54:46
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6) [REDACTED]	10 Mar 2021 14:48:54
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'no covid test documented in medical records for this hospital admission.' (Site from Safety).	(b) (4), (b) (6) [REDACTED]	10 Mar 2021 00:37:33

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Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:58:40

[Narrative](#)

Audit	User	Time (GMT)
User entered 'ON 05FEB2021 SUBJECT WAS AT SITE FOR OPEN LABEL VISIT WHICH WAS NOT COMPLETED BECAUSE OF BP 175/132 AND IRREGULAR PULSE ON EXAM. HE WAS ASYMPTOMATIC. AT THAT TIME SUBJECT STATED THAT HE HAD ARRANGED TO SEE HIS PCP OR CARDIOLOGIST AT LOCAL HOSPITAL IMMEDIATELY. INSTEAD HE WENT TO THE SUPERBOWL IN FLORIDA. AT PHONE CALL 16FEB21 SUBJECT REPORTED ANGINA 11FEB21 FOR WHICH HE VISITED ER. HE WAS ADMITTED AND A CORONARY STENT WAS PLACED 12FEB21. SUBJECT WAS DISCHARGED 13FEB21 ON ATORVASTATIN, CLOPIDOGREL, AND ISOSORBIDE MONONITRATE AS NEW MEDS. HE STATED HIS POST-STENT BP'S WERE IN THE 130'S/80'S. WILL PROCURE MEDICAL RECORDS.Update:03/09/21Med records reviewed.Subj has known h/o coronary artery disease and stent x2 to LAD in 2017 who had onset of chest pain starting 2/10/2021 at approx 20:00.He presented to ER on 2/11/2021 and was subsequently admitted with unstable angina. He underwent PCI with PTCA and stent placement on 2/12/2021 before leaving against medical advice on 2/13/2021.was hypertensive on presentation (185/103) to ER with last inpatient BP of 140/97.EKG showed NSR, rate of 73 without acute ST wave abnormality.Troponin levels remained <0.01ng/ml.CXR showed vascular calcifications present in mediastinum (consistent with known h/o CAD) and degenerative changes of thoracic spine (known h/o DJD of lumbar spine) but was otherwise normal.Cardiac PET stress (2/12/21) with abnormal myocardial perfusion scan showing moderate sized, moderate in severity mostly reversible defect consistent with ischemia in anterior wall in territory typical of LAD, moderate coronary artery calcification. treated with aspirin PO and nitroglycerin SL in ER on 2/11/21.On 2/12/21, he underwent cardiac catheterization and PCI was	(b) (4), (b) (6)	10 Mar 2021 00:29:39

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EAB) (1725)

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Form: Adverse Events (6)

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[Narrative](#)

Audit	User	Time (GMT)
performed with PTCA followed by stenting of the mid to distal LAD in overlapping fashion with a more distal LAD drug-eluting stent, bivalirudin bolus followed by infusion was administered; no complications.He will continue to follow-up with cardiology' reason for change: Data Entry Error Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response' answered with 'medical records sent to PVG 17Feb2021' (Site from Safety).	(b) (4), (b) (6)	06 Mar 2021 19:13:12
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 14:34:21
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 14:34:06
User entered 'On 05Feb2021 subject was at site for open label visit which was not completed because of BP 175/132 and irregular pulse on exam. He was asymptomatic. At that time subject stated that he had arranged to see his PCP or cardiologist at local hospital immediately. Instead he went to the superbowl in Florida. At phone call 16Feb21 subject reported angina 11Feb21 for which he visited ER. He was admitted and a coronary stent was placed 12Feb21. Subject was discharged 13Feb21 on atorvastatin, clopidogrel, and isosorbide mononitrate as new meds. He stated his post-stent BP's were in the 130's/80's. Will procure medical records'	(b) (4), (b) (6)	17 Feb 2021 19:24:34



**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:58:40**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Feb 2021 19:24:34

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:58:40**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Feb 2021 19:24:34

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:58:40**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	17 Feb 2021 19:24:34

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 16:58:40**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:16

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:58:40

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:16
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User coded data point as SOC: Metabolism and nutrition disorders, HLT: Electrolyte and fluid balance conditions, HLT: Sodium imbalance, PT: Hyponatraemia, LLT: Hyponatremia - version MedDRA\\23.0.	Coder Import (b) (4)	10 Mar 2021 23:57:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Mar 2021 23:57:40
Data point term sent to Coder	System	10 Mar 2021 23:57:22
User entered 'Hyponatremia'	Karol Moore (b) (4)	10 Mar 2021 23:57:09
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 16:58:40**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:16
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'Yes (Y)'	(b) (4)	
	Karol Moore (b) (4)	10 Mar 2021 23:57:09
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 16:58:40**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:16
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'No (N)'	(b) (4)	
	Karol Moore (b) (4)	10 Mar 2021 23:57:09
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 16:58:40**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:16
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'No (N)'	(b) (4)	
	Karol Moore (b) (4)	10 Mar 2021 23:57:09
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:16
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '16 Dec 2020'	(b) (4)	
	Karol Moore (b) (4)	10 Mar 2021 23:57:09
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 16:58:40**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:16
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered empty.	(b) (4)	
	Karol Moore (b) (4)	10 Mar 2021 23:57:09
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 16:58:40**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:16
User entered empty.	System	10 Mar 2021 23:57:09

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 16:58:40**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:16
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'No (N)'	(b) (4)	
	Karol Moore (b) (4)	10 Mar 2021 23:57:09
	(b) (4)	

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**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 16:58:40**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:16
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '18 Dec 2020'	(b) (4)	
	Karol Moore (b) (4)	10 Mar 2021 23:57:09
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 16:58:40**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:16
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered empty.	(b) (4)	
	Karol Moore (b) (4)	10 Mar 2021 23:57:09
	(b) (4)	

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 16:58:40**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:16
User entered empty.	System	10 Mar 2021 23:57:09

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 16:58:40**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:16
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4)	
	Karol Moore (b) (4)	10 Mar 2021 23:57:09
	(b) (4)	



**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 16:58:40**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:16
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'No (N)'	(b) (4)	
	Karol Moore (b) (4)	10 Mar 2021 23:57:09
	(b) (4)	

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 16:58:40**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:16
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	(b) (4)	
	Karol Moore (b) (4)	10 Mar 2021 23:57:09
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 16:58:40**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:16
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	(b) (4)	
	Karol Moore (b) (4)	10 Mar 2021 23:57:09
	(b) (4)	

**US3312130**

**Folder: Adverse Events**

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**Generated On: 09 Jun 2021 16:58:40**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:16
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	(b) (4)	
	Karol Moore (b) (4)	10 Mar 2021 23:57:09
	(b) (4)	

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 16:58:40**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:16
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered empty.	(b) (4)	
	Karol Moore (b) (4)	10 Mar 2021 23:57:09
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 16:58:40**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:16
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered empty.	(b) (4)	
	Karol Moore (b) (4)	10 Mar 2021 23:57:09
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 16:58:40**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:16
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered empty.	(b) (4)	
	Karol Moore (b) (4)	10 Mar 2021 23:57:09
	(b) (4)	

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:16
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered empty.	(b) (4)	
	Karol Moore (b) (4)	10 Mar 2021 23:57:09
	(b) (4)	



**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 16:58:40**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:16
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	(b) (4)	
	Karol Moore (b) (4)	10 Mar 2021 23:57:09
	(b) (4)	

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 16:58:40**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:16
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	(b) (4)	
	Karol Moore (b) (4)	10 Mar 2021 23:57:09
	(b) (4)	

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 16:58:40**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:16
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	(b) (4)	
	Karol Moore (b) (4)	10 Mar 2021 23:57:09
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 16:58:40**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:16
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'Not Related (NOT RELATED)'	(b) (4)	
	Karol Moore (b) (4)	10 Mar 2021 23:57:09
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:16
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'Not Related (NOT RELATED)'	(b) (4)	
	Karol Moore (b) (4)	10 Mar 2021 23:57:09
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 16:58:40**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:16
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	
	Karol Moore (b) (4)	10 Mar 2021 23:57:09
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 16:58:40**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:16
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'I'	(b) (4)	
	Karol Moore (b) (4)	10 Mar 2021 23:57:09
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 16:58:40**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:16
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	(b) (4)	
	Karol Moore (b) (4)	10 Mar 2021 23:57:09
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 16:58:40**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:16
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	(b) (4)	
	Karol Moore (b) (4)	10 Mar 2021 23:57:09
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 16:58:40**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:16
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Mar 2021 23:57:09

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 16:58:40**

[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 11:05:16
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered empty.	(b) (4)	
	Karol Moore (b) (4)	10 Mar 2021 23:57:09
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:16
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered empty.	(b) (4)	
	Karol Moore (b) (4)	10 Mar 2021 23:57:09
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 16:58:40**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:16
User entered '0'	System	10 Mar 2021 23:57:09

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 16:58:40**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:16
User entered '1'	System	10 Mar 2021 23:57:09

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 16:58:40**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:16

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:58:40

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Lower respiratory tract disorders (excl obstruction and infection), HLT: Lower respiratory tract inflammatory and immunologic conditions, PT: Pulmonary granuloma, LLT: Pulmonary granuloma - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Mar 2021 06:57:58
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Mar 2021 06:57:58
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:47:21
Data point term sent to Coder	System	10 Mar 2021 23:58:23
User entered 'calcified granuloma left mid lung'	Karol Moore (b) (4) (b) (4)	10 Mar 2021 23:58:21



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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 16:58:40**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'Yes (Y)'	Karol Moore (b) (4)	10 Mar 2021 23:58:21

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 16:58:40**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'No (N)'	Karol Moore (b) (4)	10 Mar 2021 23:58:21

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 16:58:40**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'No (N)'	Karol Moore (b) (4)	10 Mar 2021 23:58:21

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '16 Dec 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Mar 2021 23:58:21

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 16:58:40**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered empty.	Karol Moore (b) (4)	10 Mar 2021 23:58:21

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 16:58:40**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Mar 2021 23:58:21

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 16:58:40**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'Yes (Y)'	Karol Moore (b) (4)	10 Mar 2021 23:58:21

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

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*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered empty.	Karol Moore (b) (4)	10 Mar 2021 23:58:21



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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 16:58:40**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered empty.	Karol Moore (b) (4)	10 Mar 2021 23:58:21

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 16:58:40**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Mar 2021 23:58:21

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 16:58:40**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'Grade 1/Mild (Grade 1/Mild)'	Karol Moore (b) (4)	10 Mar 2021 23:58:21

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:58:40

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Mar 2021 23:58:21

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 16:58:40**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	Karol Moore (b) (4)	10 Mar 2021 23:58:21

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 16:58:40**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	Karol Moore (b) (4)	10 Mar 2021 23:58:21

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 16:58:40**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	Karol Moore (b) (4)	10 Mar 2021 23:58:21

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 16:58:40**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered empty.	Karol Moore (b) (4)	10 Mar 2021 23:58:21



**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 16:58:40**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered empty.	Karol Moore (b) (4)	10 Mar 2021 23:58:21

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 16:58:40**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered empty.	Karol Moore (b) (4)	10 Mar 2021 23:58:21

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 16:58:40**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered empty.	Karol Moore (b) (4)	10 Mar 2021 23:58:21

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 16:58:40**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	Karol Moore (b) (4)	10 Mar 2021 23:58:21

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	Karol Moore (b) (4)	10 Mar 2021 23:58:21

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	Karol Moore (b) (4)	10 Mar 2021 23:58:21

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'Not Related (NOT RELATED)'	Karol Moore (b) (4)	10 Mar 2021 23:58:21

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**Form: Adverse Events (8)**

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Mar 2021 23:58:21



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[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	
	Karol Moore (b) (4)	10 Mar 2021 23:58:21
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 16:58:40**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'I'	Karol Moore (b) (4)	10 Mar 2021 23:58:21

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	Karol Moore (b) (4)	10 Mar 2021 23:58:21

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	Karol Moore (b) (4)	10 Mar 2021 23:58:21

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Mar 2021 23:58:21

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**Folder: Adverse Events**

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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)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered empty.	Karol Moore (b) (4)	10 Mar 2021 23:58:21

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered empty.	Karol Moore (b) (4)	10 Mar 2021 23:58:21

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	10 Mar 2021 23:58:21



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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 16:58:40**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	10 Mar 2021 23:58:21

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**Folder: Adverse Events**

**Form: Adverse Events (9)**

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:26

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Folder: Adverse Events

Form: Adverse Events (9)

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:26
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:18:30
User closed query 'Per DM CLR - RQ: Site's response noted. However, if this is a worsening of the patient's ongoing Med History condition of CHRONIC KIDNEY DISEASE STAGE 3, please update the AE term to reflect the worsening of this condition (e.g., Worsening Acute Kidney Injury). Review and update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Apr 2021 06:21:57
User coded data point as SOC: Renal and urinary disorders, HLGT: Renal disorders (excl nephropathies), HLT: Renal failure and impairment, PT: Acute kidney injury, LLT: Acute kidney injury - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Apr 2021 04:57:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Apr 2021 04:57:48
Data point term sent to Coder	System	07 Apr 2021 21:48:44
Query 'Per DM CLR - RQ: Site's response noted. However, if this is a worsening of the patient's ongoing Med History condition of CHRONIC KIDNEY DISEASE STAGE 3, please update the AE term to reflect the worsening of this condition (e.g., Worsening Acute Kidney Injury). Review and update eCRF as appropriate.	(b) (4), (b) (6)	07 Apr 2021 21:48:16
' answered with 'updated' (Site from DM).		
Coding entries removed.	(b) (4), (b) (6)	07 Apr 2021 21:47:57
User entered 'worsening of ACUTE KIDNEY INJURY' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 21:47:57

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Folder: Adverse Events

Form: Adverse Events (9)

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[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR - RQ: Site's response noted. However, if this is a worsening of the patient's ongoing Med History condition of CHRONIC KIDNEY DISEASE STAGE 3, please update the AE term to reflect the worsening of this condition (e.g., Worsening Acute Kidney Injury). Review and update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 02:29:21
User closed query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of CHRONIC KIDNEY DISEASE STAGE 3. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 11:10:44
User coded data point as SOC: Renal and urinary disorders, HLGT: Renal disorders (excl nephropathies), HLT: Renal failure and impairment, PT: Acute kidney injury, LLT: Acute on chronic renal failure - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Mar 2021 09:37:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Mar 2021 09:37:41
Query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of CHRONIC KIDNEY DISEASE STAGE 3. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify. ' answered with 'UPdated' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 19:51:06
Data point term sent to Coder	System	25 Mar 2021 19:50:47
Coding entries removed.	(b) (4), (b) (6)	25 Mar 2021 19:50:26
Signature has been broken.	(b) (4), (b) (6)	25 Mar 2021 19:50:26
User entered 'ACUTE KIDNEY INJURY on chronic kidney disease' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Mar 2021 19:50:26

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Folder: Adverse Events

Form: Adverse Events (9)

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[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of CHRONIC KIDNEY DISEASE STAGE 3. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6) (b) (4)	24 Mar 2021 02:57:00
	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:47:21
User coded data point as SOC: Renal and urinary disorders, HLGT: Renal disorders (excl nephropathies), HLT: Renal failure and impairment, PT: Acute kidney injury, LLT: Acute kidney injury - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Mar 2021 00:14:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Mar 2021 00:14:40
Data point term sent to Coder	System	11 Mar 2021 00:14:00
User entered 'acute kidney injury'	Karol Moore (b) (4) (b) (4)	11 Mar 2021 00:13:12

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**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 16:58:40**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:26
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'Yes (Y)'	(b) (4)	
	Karol Moore (b) (4)	11 Mar 2021 00:13:12
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 16:58:40**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:26
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'No (N)'	(b) (4)	
	Karol Moore (b) (4)	11 Mar 2021 00:13:12
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (9)**

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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 11:05:26
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'No (N)'	(b) (4)	
	Karol Moore (b) (4)	11 Mar 2021 00:13:12
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:26
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '16 Dec 2020'	(b) (4)	
	Karol Moore (b) (4)	11 Mar 2021 00:13:12
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 16:58:40**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:26
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered empty.	(b) (4)	
	Karol Moore (b) (4)	11 Mar 2021 00:13:12
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 16:58:40**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:26
User entered empty.	System	11 Mar 2021 00:13:12

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**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 16:58:40**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:26
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'No (N)'	(b) (4)	
	Karol Moore (b) (4)	11 Mar 2021 00:13:12
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 16:58:40**

**If not Ongoing, end date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:26
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '17 Dec 2020'	(b) (4)	
	Karol Moore (b) (4)	11 Mar 2021 00:13:12
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 16:58:40**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:26
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered empty.	(b) (4)	
	Karol Moore (b) (4)	11 Mar 2021 00:13:12
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 16:58:40**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:26
User entered empty.	System	11 Mar 2021 00:13:12

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**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 16:58:40**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:26
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4)	
	Karol Moore (b) (4)	11 Mar 2021 00:13:12
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 16:58:40**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:26
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'No (N)'	(b) (4)	
	Karol Moore (b) (4)	11 Mar 2021 00:13:12
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 16:58:40**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:26
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	(b) (4)	
	Karol Moore (b) (4)	11 Mar 2021 00:13:12
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 16:58:40**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:26
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	(b) (4)	
	Karol Moore (b) (4)	11 Mar 2021 00:13:12
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 16:58:40**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:26
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	(b) (4)	
	Karol Moore (b) (4)	11 Mar 2021 00:13:12
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 16:58:40**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:26
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered empty.	(b) (4)	
	Karol Moore (b) (4)	11 Mar 2021 00:13:12
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 16:58:40**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:26
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered empty.	(b) (4)	
	Karol Moore (b) (4)	11 Mar 2021 00:13:12
	(b) (4)	

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 16:58:40**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:26
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered empty.	(b) (4)	
	Karol Moore (b) (4)	11 Mar 2021 00:13:12
	(b) (4)	

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 16:58:40**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:26
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered empty.	(b) (4)	
	Karol Moore (b) (4)	11 Mar 2021 00:13:12
	(b) (4)	



**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 16:58:40**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:26
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	(b) (4)	
	Karol Moore (b) (4)	11 Mar 2021 00:13:12
	(b) (4)	

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 16:58:40**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:26
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	(b) (4)	
	Karol Moore (b) (4)	11 Mar 2021 00:13:12
	(b) (4)	

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 16:58:40**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:26
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	(b) (4)	
	Karol Moore (b) (4)	11 Mar 2021 00:13:12
	(b) (4)	

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 16:58:40**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:26
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'Not Related (NOT RELATED)'	(b) (4)	
	Karol Moore (b) (4)	11 Mar 2021 00:13:12
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 16:58:40**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:26
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'Not Related (NOT RELATED)'	(b) (4)	
	Karol Moore (b) (4)	11 Mar 2021 00:13:12
	(b) (4)	

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 16:58:40**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:26
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	
	Karol Moore (b) (4)	11 Mar 2021 00:13:12
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 16:58:40**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:26
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	(b) (4)	
	Karol Moore (b) (4)	11 Mar 2021 00:13:12
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 16:58:40**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:26
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'I'	(b) (4)	
	Karol Moore (b) (4)	11 Mar 2021 00:13:12
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 16:58:40**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:26
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	(b) (4)	
	Karol Moore (b) (4)	11 Mar 2021 00:13:12
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 16:58:40**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:26
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Mar 2021 00:13:12

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**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 16:58:40**

[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 11:05:26
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered empty.	(b) (4)	
	Karol Moore (b) (4)	11 Mar 2021 00:13:12
	(b) (4)	

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 16:58:40**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:26
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered empty.	(b) (4)	
	Karol Moore (b) (4)	11 Mar 2021 00:13:12
	(b) (4)	

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 16:58:40**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:26
User entered '0'	System	11 Mar 2021 00:13:12

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 16:58:40**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:26
User entered 'I'	System	11 Mar 2021 00:13:12

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 16:58:40**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:05:26

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:58:40

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User coded data point as SOC: Investigations, HLT: Cardiac and vascular investigations (excl enzyme tests), HLT: Heart rate and pulse investigations, PT: Heart rate irregular, LLT: Heartbeats irregular - version MedDRA\\23.0.	Coder Import (b) (4)	11 Mar 2021 00:16:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Mar 2021 00:16:40
Data point term sent to Coder	System	11 Mar 2021 00:16:00
User entered 'irregular heartbeat'	Karol Moore (b) (4)	11 Mar 2021 00:15:26



**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 16:58:40**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'Yes (Y)'	Karol Moore (b) (4)	11 Mar 2021 00:15:26

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 16:58:40**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'No (N)'	Karol Moore (b) (4)	11 Mar 2021 00:15:26

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 16:58:40**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'No (N)'	Karol Moore (b) (4)	11 Mar 2021 00:15:26

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '05 Feb 2021'	Karol Moore (b) (4)	11 Mar 2021 00:15:26

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 16:58:40**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered empty.	Karol Moore (b) (4)	11 Mar 2021 00:15:26

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**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 16:58:40**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Mar 2021 00:15:26

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:58:40

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	11 Mar 2021 00:18:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Mar 2021 00:18:08
User entered 'Yes (Y)' reason for change: Data Entry Error	Karol Moore (b) (4)	11 Mar 2021 00:18:08
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	11 Mar 2021 00:15:26
User entered empty.	System	11 Mar 2021 00:15:26
	Karol Moore (b) (4)	11 Mar 2021 00:15:26
	(b) (4)	

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 16:58:40**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered empty.	Karol Moore (b) (4)	11 Mar 2021 00:15:26



**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 16:58:40**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered empty.	Karol Moore (b) (4)	11 Mar 2021 00:15:26

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 16:58:40**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Mar 2021 00:15:26

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 16:58:40**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4)	
	Karol Moore (b) (4)	11 Mar 2021 00:15:26
	(b) (4)	

US3312130

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:58:40

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Mar 2021 00:15:26

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 16:58:40**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	Karol Moore (b) (4)	11 Mar 2021 00:15:26

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 16:58:40**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	Karol Moore (b) (4)	11 Mar 2021 00:15:26

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 16:58:40**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	Karol Moore (b) (4)	11 Mar 2021 00:15:26

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 16:58:40**

**Hospital Admission Date (dd MMM yyyy)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered empty.	Karol Moore (b) (4)	11 Mar 2021 00:15:26



**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 16:58:40**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered empty.	Karol Moore (b) (4)	11 Mar 2021 00:15:26

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 16:58:40**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered empty.	Karol Moore (b) (4)	11 Mar 2021 00:15:26

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 16:58:40**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered empty.	Karol Moore (b) (4)	11 Mar 2021 00:15:26

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 16:58:40**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	Karol Moore (b) (4)	11 Mar 2021 00:15:26

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 16:58:40**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	Karol Moore (b) (4)	11 Mar 2021 00:15:26

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 16:58:40**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	Karol Moore (b) (4)	11 Mar 2021 00:15:26

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 16:58:40**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Mar 2021 00:15:26

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 16:58:40**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'Not Related (NOT RELATED)'	Karol Moore (b) (4)	11 Mar 2021 00:15:26



**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'Dose Delayed (DOSE DELAYED)'	Karol Moore (b) (4)	11 Mar 2021 00:15:26

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 16:58:40**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'I'	Karol Moore (b) (4)	11 Mar 2021 00:15:26

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 16:58:40**

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	Karol Moore (b) (4)	11 Mar 2021 00:15:26

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	Karol Moore (b) (4)	11 Mar 2021 00:15:26

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Mar 2021 00:15:26

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**Folder: Adverse Events**

**Form: Adverse Events (10)**

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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)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered empty.	Karol Moore (b) (4)	11 Mar 2021 00:15:26

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 16:58:40**

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered empty.	Karol Moore (b) (4)	11 Mar 2021 00:15:26

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 16:58:40**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	11 Mar 2021 00:15:26



**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 16:58:40**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Mar 2021 00:15:26

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Folder: Adverse Events

Form: Adverse Events (11)

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[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User closed query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of DEGENERATIVE DISC DISEASE. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 06:22:06
Query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of DEGENERATIVE DISC DISEASE. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify. ' answered with 'separate AEs, correct as entered, this is thoracic and med hx is lumbar (updated med hx)' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 21:50:21
User opened query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of DEGENERATIVE DISC DISEASE. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 02:54:21
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthritis, PT: Spinal osteoarthritis, LLT: Thoracic spine degeneration - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Mar 2021 11:25:55
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Mar 2021 11:25:55
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:47:21
Data point term sent to Coder	System	11 Mar 2021 00:18:01

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:58:40

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'THORACIC SPINE DEGENERATIVE CHANGES' reason for change: Data Entry Error	Karol Moore (b) (4)	11 Mar 2021 00:17:11
User entered 'THORACIC SPINE DEGENERATIVE CHANGES' reason for change: Data Entry Error	Karol Moore (b) (4)	11 Mar 2021 00:17:05
Data point term sent to Coder	System	11 Mar 2021 00:17:01
User entered 'thoracic spine degeneration changes'	Karol Moore (b) (4)	11 Mar 2021 00:16:30

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**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 16:58:40**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'Yes (Y)'	Karol Moore (b) (4)	11 Mar 2021 00:16:30

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**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 16:58:40**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'No (N)'	Karol Moore (b) (4)	11 Mar 2021 00:16:30

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 16:58:40**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'No (N)'	Karol Moore (b) (4)	11 Mar 2021 00:16:30

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '11 Feb 2021'	Karol Moore (b) (4)	11 Mar 2021 00:16:30

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 16:58:40**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered empty.	Karol Moore (b) (4)	11 Mar 2021 00:16:30



**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 16:58:40**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Mar 2021 00:16:30

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 16:58:40**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'Yes (Y)'	Karol Moore (b) (4)	11 Mar 2021 00:16:30

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**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 16:58:40**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered empty.	Karol Moore (b) (4)	11 Mar 2021 00:16:30

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**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 16:58:40**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered empty.	Karol Moore (b) (4)	11 Mar 2021 00:16:30

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 16:58:40**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Mar 2021 00:16:30

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 16:58:40**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'Grade 1/Mild (Grade 1/Mild)'	Karol Moore (b) (4)	11 Mar 2021 00:16:30

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 16:58:40**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'No (N)'	Karol Moore (b) (4)	11 Mar 2021 00:16:30

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 16:58:40**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	Karol Moore (b) (4)	11 Mar 2021 00:16:30



**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 16:58:40**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	Karol Moore (b) (4)	11 Mar 2021 00:16:30

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 16:58:40**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	Karol Moore (b) (4)	11 Mar 2021 00:16:30

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 16:58:40**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered empty.	Karol Moore (b) (4)	11 Mar 2021 00:16:30

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 16:58:40**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered empty.	Karol Moore (b) (4)	11 Mar 2021 00:16:30

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 16:58:40**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered empty.	Karol Moore (b) (4)	11 Mar 2021 00:16:30

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered empty.	Karol Moore (b) (4)	11 Mar 2021 00:16:30

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 16:58:40**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	Karol Moore (b) (4)	11 Mar 2021 00:16:30

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 16:58:40**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	Karol Moore (b) (4)	11 Mar 2021 00:16:30



**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 16:58:40**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	Karol Moore (b) (4)	11 Mar 2021 00:16:30

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 16:58:40**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'Not Related (NOT RELATED)'	Karol Moore (b) (4)	11 Mar 2021 00:16:30

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 16:58:40**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'Not Related (NOT RELATED)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Mar 2021 00:16:30

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 16:58:40**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	
	Karol Moore (b) (4)	11 Mar 2021 00:16:30
	(b) (4)	

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 16:58:40**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'I'	Karol Moore (b) (4)	11 Mar 2021 00:16:30

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 16:58:40**

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	Karol Moore (b) (4)	11 Mar 2021 00:16:30

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 16:58:40**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered '0'	Karol Moore (b) (4)	11 Mar 2021 00:16:30

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 16:58:40**

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Mar 2021 00:16:30



**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 16:58:40**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered empty.	Karol Moore (b) (4)	11 Mar 2021 00:16:30

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 16:58:40**

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:45:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:41
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:47:21
User entered empty.	Karol Moore (b) (4)	11 Mar 2021 00:16:30

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 16:58:40**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	11 Mar 2021 00:16:30

**US3312130**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 16:58:40**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Mar 2021 00:16:30

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 09 Jun 2021 16:58:40**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:25:47
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:46:11
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Yes (Y)'	(b) (4)	21 Aug 2020 19:17:33
	Karol Moore (b) (4)	
	(b) (4)	

US3312130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:58:40

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
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 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 23:28:24
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 23:28:24
Data point term sent to Coder	System	21 Aug 2020 19:18:57
User entered 'acetylsalicylic acid'	Karol Moore (b) (4)	21 Aug 2020 19:18:22

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:18:22

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'Coronary artery disease'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:18:22



**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '81'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:18:22

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'mg (mg)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:18:22

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:58:40**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:18:22

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'once daily (QD)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:18:22

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:58:40**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:18:22

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'Oral (ORAL)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:18:22

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:58:40**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:18:22

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '13 Nov 2017'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:18:22



**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:18:22

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:18:22

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:58:40**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:18:22

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:18:22

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 19:18:22

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 19:18:22

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 19:18:22

US3312130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:58:40

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL, PRODUCTSYNONYM: COREG - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	21 Aug 2020 19:21:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 19:21:23
Data point term sent to Coder User entered 'coreg'	System Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:19:59 21 Aug 2020 19:19:01



**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:19:01

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'hypertension'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:19:01

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '12'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:19:01

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'mg (mg)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:19:01

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:58:40**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:19:01

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'twice daily (BID)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:19:01

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:58:40**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:19:01

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'Oral (ORAL)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:19:01



**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:58:40**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:19:01

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '13 Nov 2017'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:19:01

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:19:01

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:19:01

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:58:40**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:19:01

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:19:01

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	21 Aug 2020 19:19:01

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 19:19:01



**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 19:19:01

US3312130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:58:40

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SULFONYLUREAS, PRODUCT: GLIPIZIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	21 Aug 2020 19:21:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 19:21:23
Data point term sent to Coder	System	21 Aug 2020 19:20:01
User entered 'glipizide'	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:19:50

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:58:40**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'No (N)'	(b) (4)	
	Karol Moore (b) (4)	21 Aug 2020 19:19:50
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:58:40**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'Diabetes Mellitus Type II'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:19:50

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:58:40**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '5'	(b) (4)	
	Karol Moore (b) (4)	21 Aug 2020 19:19:50
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:58:40**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'mg (mg)'	(b) (4)	
	Karol Moore (b) (4)	21 Aug 2020 19:19:50
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:58:40**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4)	
	Karol Moore (b) (4)	21 Aug 2020 19:19:50
	(b) (4)	

US3312130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:58:40

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'three times daily (TID)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:19:50



**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:58:40**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4)	
	Karol Moore (b) (4)	21 Aug 2020 19:19:50
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:58:40**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'Oral (ORAL)'	(b) (4)	
	Karol Moore (b) (4)	21 Aug 2020 19:19:50
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:58:40**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4)	21 Aug 2020 19:19:50
	Karol Moore (b) (4)	
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '01 Jan 2019'	(b) (4)	
	Karol Moore (b) (4)	21 Aug 2020 19:19:50
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '0'	(b) (4)	
	Karol Moore (b) (4)	21 Aug 2020 19:19:50
	(b) (4)	

US3312130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:58:40

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 17:57:26
User entered 'Yes (Y)'	Karol Moore (b) (4)	21 Aug 2020 19:19:50

US3312130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:58:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '11 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 17:57:26
User entered empty.	Karol Moore (b) (4)	21 Aug 2020 19:19:50

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:58:40**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'No (N)'	(b) (4)	
	Karol Moore (b) (4)	21 Aug 2020 19:19:50
	(b) (4)	



**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:58:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:50
User entered '3'	System	21 Aug 2020 19:19:50

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:58:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:50
User entered '1'	System	21 Aug 2020 19:19:50

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:58:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:50
User entered '804 (804)'	System	21 Aug 2020 19:19:50

US3312130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:58:40

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 19:22:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 19:22:26
Data point term sent to Coder	System	21 Aug 2020 19:21:06
User entered 'metformin'	Karol Moore (b) (4)	21 Aug 2020 19:20:44

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:58:40**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:20:44

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:58:40**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'Diabetes Mellitus Type II'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:20:44

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:58:40**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '1000'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:20:44

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:58:40**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'mg (mg)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:20:44



**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:58:40**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:20:44

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:58:40**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'twice daily (BID)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:20:44

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:58:40**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:20:44

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:58:40**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'Oral (ORAL)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:20:44

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:58:40**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:20:44

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '13 Nov 2017'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:20:44

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:20:44

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:58:40**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:20:44



**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:58:40**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:20:44

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:58:40**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:20:44

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:58:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	21 Aug 2020 19:20:44

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:58:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 19:20:44

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:58:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 19:20:44

US3312130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:58:40

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SODIUM-GLUCOSE CO-TRANSPORTER 2 (SGLT2) INHIBITORS, PRODUCT: DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE, PRODUCTSYNONYM: FARXIGA - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	22 Aug 2020 06:47:12
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	22 Aug 2020 06:47:12
Data point term sent to Coder	System	21 Aug 2020 19:22:08
User entered 'favxiga'	Karol Moore (b) (4)	21 Aug 2020 19:21:21
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:58:40**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'No (N)'	(b) (4)	
	Karol Moore (b) (4)	21 Aug 2020 19:21:21
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:58:40**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'Diabetes Mellitus Type II'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:21:21



**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:58:40**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '10'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:21:21

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:58:40**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'mg (mg)'	(b) (4)	
	Karol Moore (b) (4)	21 Aug 2020 19:21:21
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:58:40**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4)	
	Karol Moore (b) (4)	21 Aug 2020 19:21:21
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:58:40**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'once daily (QD)'	(b) (4)	
	Karol Moore (b) (4)	21 Aug 2020 19:21:21
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:58:40**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4)	
	Karol Moore (b) (4)	21 Aug 2020 19:21:21
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:58:40**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'Oral (ORAL)'	(b) (4)	
	Karol Moore (b) (4)	21 Aug 2020 19:21:21
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:58:40**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4)	21 Aug 2020 19:21:21
	Karol Moore (b) (4)	
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '19 Feb 2020'	(b) (4)	
	Karol Moore (b) (4)	21 Aug 2020 19:21:21
	(b) (4)	



**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '0'	(b) (4)	
	Karol Moore (b) (4)	21 Aug 2020 19:21:21
	(b) (4)	

US3312130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:58:40

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	08 Apr 2021 17:57:55
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	21 Aug 2020 19:21:21

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:58:40**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '11 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 17:57:55
User entered empty.	Karol Moore (b) (4)	21 Aug 2020 19:21:21

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:58:40**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:55
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'No (N)'	(b) (4)	
	Karol Moore (b) (4)	21 Aug 2020 19:21:21
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:58:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:55
User entered '1'	System	21 Aug 2020 19:21:21

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:58:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:55
User entered '1'	System	21 Aug 2020 19:21:21

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:58:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:55
User entered '804 (804)'	System	21 Aug 2020 19:21:21

US3312130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:58:40

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:58
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Jan 2021 14:14:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Jan 2021 14:14:51
Data point term sent to Coder	System	15 Jan 2021 14:13:46
User entered 'acetaminophen'	Karol Moore (b) (4)	15 Jan 2021 14:13:20
	(b) (4)	



US3312130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:58:40

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:58
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	15 Jan 2021 14:25:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Jan 2021 14:25:53
User entered 'No (N)' reason for change: Data Entry Error	Karol Moore (b) (4)	15 Jan 2021 14:25:53
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	15 Jan 2021 14:13:20
User entered empty.	System	15 Jan 2021 14:13:20
	Karol Moore (b) (4)	15 Jan 2021 14:13:20
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:58:40**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:58
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'symptomatic covid-19'	(b) (4) Karol Moore (b) (4) (b) (4)	15 Jan 2021 14:13:20

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:58:40**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:58
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '1000'	(b) (4)	
	Karol Moore (b) (4)	15 Jan 2021 14:13:20
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:58:40**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:58
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'mg (mg)'	(b) (4)	
	Karol Moore (b) (4)	15 Jan 2021 14:13:20
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:58:40**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:58
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4)	
	Karol Moore (b) (4)	15 Jan 2021 14:13:20
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:58:40**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:58
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'as needed (PRN)'	(b) (4)	
	Karol Moore (b) (4)	15 Jan 2021 14:13:20
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:58:40**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:58
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4)	
	Karol Moore (b) (4)	15 Jan 2021 14:13:20
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:58:40**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:58
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'Oral (ORAL)'	(b) (4)	
	Karol Moore (b) (4)	15 Jan 2021 14:13:20
	(b) (4)	



**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:58:40**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:58
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4)	
	Karol Moore (b) (4)	15 Jan 2021 14:13:20
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:58
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '15 Dec 2020'	(b) (4)	
	Karol Moore (b) (4)	15 Jan 2021 14:13:20
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:58
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	15 Jan 2021 14:13:20

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:58:40**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:58
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'No (N)'	(b) (4)	
	Karol Moore (b) (4)	15 Jan 2021 14:13:20
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:58:40**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:58
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '25 Dec 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	15 Jan 2021 14:13:20

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:58:40**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:58
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'No (N)'	(b) (4)	
	Karol Moore (b) (4)	15 Jan 2021 14:13:20
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:58:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:58
User entered empty.	System	15 Jan 2021 14:13:20

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:58:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:58
User entered empty.	System	15 Jan 2021 14:13:20



**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:58:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:58
User entered empty.	System	15 Jan 2021 14:13:20

US3312130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:58:40

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:01
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS FOR PARENTERAL NUTRITION, PRODUCT: GLUCOSE, PRODUCTSYNONYM: DEXTROSE IN WATER - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	30 Mar 2021 13:09:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	30 Mar 2021 13:09:45
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history of CHRONIC KIDNEY DISEASE STAGE 3 worsened. If yes, please review if an AE reflecting worsening of corresponding MH condition should be recorded. Update all applicable eCRFs if appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 11:08:29
Data point term sent to Coder	System	25 Mar 2021 23:17:59
Coding entries removed.	(b) (4), (b) (6)	25 Mar 2021 23:17:03
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history of CHRONIC KIDNEY DISEASE STAGE 3 worsened. If yes, please review if an AE reflecting worsening of corresponding MH condition should be recorded. Update all applicable eCRFs if appropriate. ' answered with 'not a worsening, correct medra indication' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 23:16:56

US3312130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:58:40

[Name of Medication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history of CHRONIC KIDNEY DISEASE STAGE 3 worsened. If yes, please review if an AE reflecting worsening of corresponding MH condition should be recorded. Update all applicable eCRFs if appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 03:37:01
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS FOR PARENTERAL NUTRITION, PRODUCT: GLUCOSE, PRODUCTSYNONYM: DEXTROSE IN WATER - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Mar 2021 10:59:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Mar 2021 10:59:44
Data point term sent to Coder	System	23 Feb 2021 16:13:56
User entered 'DEXTROSE 10 % IN WATER' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	23 Feb 2021 16:13:15
Data point term sent to Coder	System	23 Feb 2021 16:03:45
User entered 'intravenous fluids (Dextrose 10 % In Water)'	Karol Moore (b) (4) (b) (4)	23 Feb 2021 16:02:59

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:58:40**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:01
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'No (N)'	(b) (4)	
	Karol Moore (b) (4)	23 Feb 2021 16:02:59
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:58:40**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:01
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'ACUTE KIDNEY INJURY on Chronic kidney disease' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	25 Mar 2021 23:17:03
User entered 'acute kidney injury'	Karol Moore (b) (4) (b) (4)	23 Feb 2021 16:02:59

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:58:40**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:01
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '1000'	(b) (4)	
	Karol Moore (b) (4)	23 Feb 2021 16:02:59
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:58:40**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:01
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'mL (mL)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Feb 2021 16:02:59

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:58:40**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:01
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4)	
	Karol Moore (b) (4)	23 Feb 2021 16:02:59
	(b) (4)	



**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:58:40**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:01
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'as needed (PRN)'	(b) (4)	
	Karol Moore (b) (4)	23 Feb 2021 16:02:59
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:58:40**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:01
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4)	
	Karol Moore (b) (4)	23 Feb 2021 16:02:59
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:58:40**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:01
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Feb 2021 16:02:59

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:58:40**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:01
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4)	
	Karol Moore (b) (4)	23 Feb 2021 16:02:59
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:01
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '16 Dec 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Feb 2021 16:02:59

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:01
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '0'	(b) (4)	
	Karol Moore (b) (4)	23 Feb 2021 16:02:59
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:58:40**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:01
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'No (N)'	(b) (4)	
	Karol Moore (b) (4)	23 Feb 2021 16:02:59
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:58:40**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:01
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '18 Dec 2020'	(b) (4)	
	Karol Moore (b) (4)	23 Feb 2021 16:02:59
	(b) (4)	



**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:58:40**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:01
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'No (N)'	(b) (4)	
	Karol Moore (b) (4)	23 Feb 2021 16:02:59
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:58:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:01
User entered empty.	System	23 Feb 2021 16:02:59

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:58:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:01
User entered empty.	System	23 Feb 2021 16:02:59

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:58:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:01
User entered empty.	System	23 Feb 2021 16:02:59

US3312130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:58:40

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Mar 2021 21:03:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Mar 2021 21:03:46
Data point term sent to Coder	System	23 Feb 2021 16:12:55
User entered '0.5 Normal saline with insulin 100 units'	Karol Moore (b) (4)	23 Feb 2021 16:12:28

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:58:40**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'No (N)'	(b) (4)	
	Karol Moore (b) (4)	23 Feb 2021 16:12:28
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:58:40**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'untreated diabetes'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Feb 2021 16:12:28

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:58:40**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '500'	(b) (4)	
	Karol Moore (b) (4)	23 Feb 2021 16:12:28
	(b) (4)	



**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:58:40**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'mL (mL)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Feb 2021 16:12:28

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:58:40**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4)	
	Karol Moore (b) (4)	23 Feb 2021 16:12:28
	(b) (4)	

US3312130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:58:40

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	(b) (4)	23 Feb 2021 16:12:42
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	23 Feb 2021 16:12:42
User entered 'once daily (QD)' reason for change:	Karol Moore (b) (4)	23 Feb 2021 16:12:42
Data Entry Error	(b) (4)	23 Feb 2021 16:12:28
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	23 Feb 2021 16:12:28
User entered 'once (ONCE)'	Karol Moore (b) (4)	23 Feb 2021 16:12:28
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:58:40**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4)	
	Karol Moore (b) (4)	23 Feb 2021 16:12:28
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:58:40**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Feb 2021 16:12:28

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:58:40**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4)	
	Karol Moore (b) (4)	23 Feb 2021 16:12:28
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '16 Dec 2020'	(b) (4)	
	Karol Moore (b) (4)	23 Feb 2021 16:12:28
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '0'	(b) (4)	
	Karol Moore (b) (4)	23 Feb 2021 16:12:28
	(b) (4)	



**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:58:40**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'No (N)'	(b) (4)	
	Karol Moore (b) (4)	23 Feb 2021 16:12:28
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:58:40**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '17 Dec 2020'	(b) (4)	
	Karol Moore (b) (4)	23 Feb 2021 16:12:28
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:58:40**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'No (N)'	(b) (4)	
	Karol Moore (b) (4)	23 Feb 2021 16:12:28
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:58:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:05
User entered '1'	System	23 Feb 2021 16:12:42
User entered empty.	System	23 Feb 2021 16:12:28

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:58:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:05
User entered '1'	System	23 Feb 2021 16:12:42
User entered empty.	System	23 Feb 2021 16:12:28

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:58:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:05
User entered '804 (804)'	System	23 Feb 2021 16:12:42
User entered empty.	System	23 Feb 2021 16:12:28

US3312130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:58:40

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:11
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: VASODILATORS USED IN CARDIAC DISEASES, ATC: ORGANIC NITRATES, PRODUCT: GLYCERYL TRINITRATE, PRODUCTSYNONYM: NITROGLYCERINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	09 Apr 2021 05:27:29
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 05:27:29
Data point term sent to Coder	System	08 Apr 2021 19:37:33
Coding entries removed.	(b) (4), (b) (6)	08 Apr 2021 19:37:09
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: VASODILATORS USED IN CARDIAC DISEASES, ATC: ORGANIC NITRATES, PRODUCT: GLYCERYL TRINITRATE, PRODUCTSYNONYM: NITROGLYCERINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 11:44:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 11:44:42
Data point term sent to Coder	System	23 Feb 2021 16:15:58
User entered 'nitroglycerine'	Karol Moore (b) (4) (b) (4)	23 Feb 2021 16:15:56

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:58:40**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:11
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'No (N)'	(b) (4)	
	Karol Moore (b) (4)	23 Feb 2021 16:15:56
	(b) (4)	



US3312130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:58:40

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:11
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User closed query 'Per DM CLR-RQ: Response noted. However, the corresponding AE indicates that Chest Pain is Non-Cardiac related. Please confirm and reconcile with AE eCRF so there is an appropriate match. Please also update Indication field to reflect the type of Chest Pain (e.g. Chest Pain - Cardiac Related). Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 10:11:13
Query 'Per DM CLR-RQ: Response noted. However, the corresponding AE indicates that Chest Pain is Non-Cardiac related. Please confirm and reconcile with AE eCRF so there is an appropriate match. Please also update Indication field to reflect the type of Chest Pain (e.g. Chest Pain - Cardiac Related). Update eCRF as appropriate.' answered with 'UPDATED.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 19:37:17
User entered 'CHEST PAIN - CARDIAC RELATED' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 19:37:09
User opened query 'Per DM CLR-RQ: Response noted. However, the corresponding AE indicates that Chest Pain is Non-Cardiac related. Please confirm and reconcile with AE eCRF so there is an appropriate match. Please also update Indication field to reflect the type of Chest Pain (e.g. Chest Pain - Cardiac Related). Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 16:17:41
Query 'Per DM CLR-RQ: Response noted. However, please update Indication field to reflect the type of Chest Pain (e.g. Chest Pain - Cardiac Related). Update eCRF as appropriate.	(b) (4), (b) (6)	05 Apr 2021 16:16:44
' canceled (Site from DM).		
User opened query 'Per DM CLR-RQ: Response noted. However, please update Indication field to reflect the type of Chest Pain (e.g. Chest Pain - Cardiac Related). Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 16:11:58

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US3312130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:58:40

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if CHEST PAIN is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. ' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 11:08:46
Query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if CHEST PAIN is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort.	(b) (4), (b) (6)	25 Mar 2021 23:15:58
' answered with 'cardiac' (Site from DM).		
User opened query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if CHEST PAIN is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort.	(b) (4), (b) (6)	13 Mar 2021 03:37:23
' (Site from DM).		
User entered 'chest pain'	Karol Moore (b) (4) (b) (4)	23 Feb 2021 16:15:56

US3312130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:58:40

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:11
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User closed query 'Per CDM CLR re-query: Thank you for your update, however please consider adding this as 5/20 instead of 5-20. Thank you!' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 06:30:28
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
Query 'Per CDM CLR re-query: Thank you for your update, however please consider adding this as 5/20 instead of 5-20. Thank you!' answered with 'updated' (Site from DM).	(b) (4)	
	Monica Atwood (b) (4)	09 Apr 2021 16:28:32
	(b) (4)	
User entered '5/20' reason for change: Data Entry Error	Monica Atwood (b) (4)	09 Apr 2021 16:27:27
	(b) (4)	
User opened query 'Per CDM CLR re-query: Thank you for your update, however please consider adding this as 5/20 instead of 5-20. Thank you!' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 10:11:50
User closed query 'Per DM CLR-RQ: Response noted. However, please note that only numerical values are to be reported in the Dose field. Please also confirm if actual dose administered is not known. If yes, please indicate "Unknown" in the dose field instead. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 10:11:50
Query 'Per DM CLR-RQ: Response noted. However, please note that only numerical values are to be reported in the Dose field. Please also confirm if actual dose administered is not known. If yes, please indicate "Unknown" in the dose field instead. Update eCRF as appropriate.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 18:42:47
User entered '5-20' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 18:05:03

US3312130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:58:40

[Dose per administration](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR-RQ: Response noted. However, please note that only numerical values are to be reported in the Dose field. Please also confirm if actual dose administered is not known. If yes, please indicate "Unknown" in the dose field instead. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 16:14:33
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 11:08:50
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with '5 mcg-20mcg is correct. If this is not sufficient then please specify how this should be entered' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 23:14:55
User entered '5-20 (varied dosage)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Mar 2021 23:14:21
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	21 Mar 2021 00:25:35
User closed query 'Per CDM:Please update the dose per administration with only the numeric value.Thank you' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 15:15:10
Query 'Per CDM:Please update the dose per administration with only the numeric value.Thank you' answered with 'UPDATED.' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 15:22:22
User entered '5-20' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Mar 2021 15:22:16
User opened query 'Per CDM:Please update the dose per administration with only the numeric value.Thank you' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 12:28:31
User entered '5-20 titrated'	Karol Moore (b) (4) (b) (4)	23 Feb 2021 16:15:56

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:58:40**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:11
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'ug (ug)'	(b) (4)	
	Karol Moore (b) (4)	23 Feb 2021 16:15:56
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:58:40**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:11
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4)	
	Karol Moore (b) (4)	23 Feb 2021 16:15:56
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:58:40**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:11
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'as needed (PRN)'	(b) (4)	
	Karol Moore (b) (4)	23 Feb 2021 16:15:56
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:58:40**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:11
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4)	
	Karol Moore (b) (4)	23 Feb 2021 16:15:56
	(b) (4)	



**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:58:40**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:11
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Feb 2021 16:15:56

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:58:40**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:11
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4)	
	Karol Moore (b) (4)	23 Feb 2021 16:15:56
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:11
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '16 Dec 2020'	(b) (4)	
	Karol Moore (b) (4)	23 Feb 2021 16:15:56
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:11
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '0'	(b) (4)	
	Karol Moore (b) (4)	23 Feb 2021 16:15:56
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:58:40**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:11
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'No (N)'	(b) (4)	
	Karol Moore (b) (4)	23 Feb 2021 16:15:56
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:58:40**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:11
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '17 Dec 2020'	(b) (4)	
	Karol Moore (b) (4)	23 Feb 2021 16:15:56
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:58:40**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:11
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'No (N)'	(b) (4)	
	Karol Moore (b) (4)	23 Feb 2021 16:15:56
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:58:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:11
User entered empty.	System	23 Feb 2021 16:15:56



**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:58:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:11
User entered empty.	System	23 Feb 2021 16:15:56

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:58:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:11
User entered empty.	System	23 Feb 2021 16:15:56

US3312130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:58:40

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:15
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
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)	23 Feb 2021 16:19:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Feb 2021 16:19:02
Data point term sent to Coder	System	23 Feb 2021 16:18:06
User entered 'aspirin'	Karol Moore (b) (4)	23 Feb 2021 16:17:18

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:58:40**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:15
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'No (N)'	(b) (4)	
	Karol Moore (b) (4)	23 Feb 2021 16:17:18
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:58:40**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:15
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'chest pain'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Feb 2021 16:17:18

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:58:40**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:15
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '325'	(b) (4)	
	Karol Moore (b) (4)	23 Feb 2021 16:17:18
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:58:40**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:15
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'mg (mg)'	(b) (4)	
	Karol Moore (b) (4)	23 Feb 2021 16:17:18
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:58:40**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:15
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4)	
	Karol Moore (b) (4)	23 Feb 2021 16:17:18
	(b) (4)	



**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:58:40**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:15
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'once daily (QD)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Feb 2021 16:17:18

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:58:40**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:15
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4)	
	Karol Moore (b) (4)	23 Feb 2021 16:17:18
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:58:40**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:15
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'Oral (ORAL)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Feb 2021 16:17:18

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:58:40**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:15
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4)	23 Feb 2021 16:17:18
	Karol Moore (b) (4)	
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:15
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '16 Dec 2020'	(b) (4)	
	Karol Moore (b) (4)	23 Feb 2021 16:17:18
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:15
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '0'	(b) (4)	
	Karol Moore (b) (4)	23 Feb 2021 16:17:18
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:58:40**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:15
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'No (N)'	(b) (4)	
	Karol Moore (b) (4)	23 Feb 2021 16:17:18
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:58:40**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:15
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '17 Dec 2020'	(b) (4)	
	Karol Moore (b) (4)	23 Feb 2021 16:17:18
	(b) (4)	



**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:58:40**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:15
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'No (N)'	(b) (4)	
	Karol Moore (b) (4)	23 Feb 2021 16:17:18
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:58:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:15
User entered '1'	System	23 Feb 2021 16:17:18

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:58:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:15
User entered '1'	System	23 Feb 2021 16:17:18

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:58:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:15
User entered '804 (804)'	System	23 Feb 2021 16:17:18

US3312130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:58:40

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
Query 'Per DM CLR: The corresponding AE recorded (AE# 1) does not show 'Any ConMed Administered' =Yes. Please reconcile and update applicable eCRFs as appropriate. ' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Mar 2021 03:38:25
User opened query 'Per DM CLR: The corresponding AE recorded (AE# 1) does not show 'Any ConMed Administered' =Yes. Please reconcile and update applicable eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 03:38:23
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: LABETALOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 06:29:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 06:29:07
Data point term sent to Coder	System	23 Feb 2021 16:19:07
User entered 'labetolol'	Karol Moore (b) (4) (b) (4)	23 Feb 2021 16:18:07

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:58:40**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'No (N)'	(b) (4)	
	Karol Moore (b) (4)	23 Feb 2021 16:18:07
	(b) (4)	

US3312130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:58:40

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User closed query 'Per DM CLR: The corresponding AE recorded (AE# 1) does not show 'Any ConMed Administered' =Yes. Please reconcile and update applicable eCRFs as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Mar 2021 11:09:06
Query 'Per DM CLR: The corresponding AE recorded (AE# 1) does not show 'Any ConMed Administered' =Yes. Please reconcile and update applicable eCRFs as appropriate. ' answered with 'AE of uncontrolled htn has CM noted' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 23:13:05
User opened query 'Per DM CLR: The corresponding AE recorded (AE# 1) does not show 'Any ConMed Administered' =Yes. Please reconcile and update applicable eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 03:38:35
User entered 'uncontrolled hypertension'	Karol Moore (b) (4) (b) (4)	23 Feb 2021 16:18:07

US3312130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:58:40

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User closed query 'Per CDM: Per CCG's Dose per administration should be "UNK" if data is not available.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Mar 2021 11:09:08
Query 'Per CDM: Per CCG's Dose per administration should be "UNK" if data is not available.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 23:11:36
User entered 'UNK' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Mar 2021 23:11:30
User opened query 'Per CDM: Per CCG's Dose per administration should be "UNK" if data is not available.' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 12:33:17
User entered 'un'	Karol Moore (b) (4) (b) (4)	23 Feb 2021 16:18:07



**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:58:40**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'mg (mg)'	(b) (4)	
	Karol Moore (b) (4)	23 Feb 2021 16:18:07
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:58:40**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4)	
	Karol Moore (b) (4)	23 Feb 2021 16:18:07
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:58:40**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'as needed (PRN)'	(b) (4)	
	Karol Moore (b) (4)	23 Feb 2021 16:18:07
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:58:40**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4)	
	Karol Moore (b) (4)	23 Feb 2021 16:18:07
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:58:40**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Feb 2021 16:18:07

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:58:40**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4)	23 Feb 2021 16:18:07
	Karol Moore (b) (4)	
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '16 Dec 2020'	(b) (4)	
	Karol Moore (b) (4)	23 Feb 2021 16:18:07
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '0'	(b) (4)	
	Karol Moore (b) (4)	23 Feb 2021 16:18:07
	(b) (4)	



**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:58:40**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'No (N)'	(b) (4)	
	Karol Moore (b) (4)	23 Feb 2021 16:18:07
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:58:40**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '16 Dec 2020'	(b) (4)	
	Karol Moore (b) (4)	23 Feb 2021 16:18:07
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:58:40**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'No (N)'	(b) (4)	
	Karol Moore (b) (4)	23 Feb 2021 16:18:07
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:58:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:21
User entered empty.	System	23 Feb 2021 16:18:07

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:58:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:21
User entered empty.	System	23 Feb 2021 16:18:07

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:58:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:21
User entered empty.	System	23 Feb 2021 16:18:07

US3312130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:58:40

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history of HYPERLIPIDEMIA worsened. If yes, please review if an AE reflecting worsening of corresponding MH condition should be recorded. Update all applicable eCRFs if appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Mar 2021 11:09:30
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history of HYPERLIPIDEMIA worsened. If yes, please review if an AE reflecting worsening of corresponding MH condition should be recorded. Update all applicable eCRFs if appropriate. ' answered with 'Correct as entered, not worsening, subject was not treating condition' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 23:11:00
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history of HYPERLIPIDEMIA worsened. If yes, please review if an AE reflecting worsening of corresponding MH condition should be recorded. Update all applicable eCRFs if appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 03:38:49
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Feb 2021 16:35:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Feb 2021 16:35:01
Data point term sent to Coder	System	23 Feb 2021 16:19:07
User entered 'atorvastatin'	Karol Moore (b) (4) (b) (4)	23 Feb 2021 16:18:30

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:58:40**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Feb 2021 16:18:30



**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:58:40**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'hyperlipidemia'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Feb 2021 16:18:30

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:58:40**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '80'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Feb 2021 16:18:30

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:58:40**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'mg (mg)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Feb 2021 16:18:30

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:58:40**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Feb 2021 16:18:30

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:58:40**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'once daily (QD)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Feb 2021 16:18:30

US3312130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:58:40

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Feb 2021 16:18:30

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:58:40**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'Oral (ORAL)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Feb 2021 16:18:30

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:58:40**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Feb 2021 16:18:30



**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '12 Feb 2021'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Feb 2021 16:18:30

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Feb 2021 16:18:30

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:58:40**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Feb 2021 16:18:30

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:58:40**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Feb 2021 16:18:30

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:58:40**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Feb 2021 16:18:30

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:58:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Feb 2021 16:18:30

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:58:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Feb 2021 16:18:30

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:58:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Feb 2021 16:18:30



US3312130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:58:40

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
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 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 20:54:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 20:54:05
Data point term sent to Coder	System	08 Apr 2021 18:19:35
Coding entries removed.	(b) (4), (b) (6)	08 Apr 2021 18:18:37
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 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Feb 2021 07:10:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Feb 2021 07:10:08
Data point term sent to Coder	System	23 Feb 2021 16:19:08
User entered 'clopidogral'	Karol Moore (b) (4)	23 Feb 2021 16:19:00

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:58:40**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Feb 2021 16:19:00

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:58:40**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'THROMBUS PROPHYLAXIS'	(b) (4)	08 Apr 2021 18:18:37
reason for change: Data Entry Error	(b) (4), (b) (6)	
User entered 'angina'	Karol Moore (b) (4)	23 Feb 2021 16:19:00
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:58:40**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '75'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Feb 2021 16:19:00

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:58:40**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'mg (mg)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Feb 2021 16:19:00

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:58:40**

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4)	23 Feb 2021 16:19:00
	Karol Moore (b) (4)	
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:58:40**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'once daily (QD)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Feb 2021 16:19:00

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:58:40**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Feb 2021 16:19:00



**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:58:40**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'Oral (ORAL)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Feb 2021 16:19:00

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:58:40**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Feb 2021 16:19:00

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '12 Feb 2021'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Feb 2021 16:19:00

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Feb 2021 16:19:00

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:58:40**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Feb 2021 16:19:00

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:58:40**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Feb 2021 16:19:00

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:58:40**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Feb 2021 16:19:00

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:58:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Feb 2021 16:19:00



**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:58:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Feb 2021 16:19:00

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:58:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Feb 2021 16:19:00

US3312130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:58:40

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
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)	09 Apr 2021 05:10:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Apr 2021 05:10:45
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	08 Apr 2021 18:19:34 08 Apr 2021 18:19:27
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)	23 Feb 2021 16:21:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Feb 2021 16:21:01
Data point term sent to Coder User entered 'isosorbide mononitrate'	System Karol Moore (b) (4)	23 Feb 2021 16:20:09 23 Feb 2021 16:19:33

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:58:40**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Feb 2021 16:19:33

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:58:40**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'HYPERTENTION' reason for change:	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:19:27
Data Entry Error		
User entered 'angina'	Karol Moore (b) (4) (b) (4)	23 Feb 2021 16:19:33

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:58:40**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '30'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Feb 2021 16:19:33

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:58:40**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'mg (mg)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Feb 2021 16:19:33

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:58:40**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4)	23 Feb 2021 16:19:33
	Karol Moore (b) (4)	
	(b) (4)	



**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:58:40**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'once daily (QD)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Feb 2021 16:19:33

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:58:40**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Feb 2021 16:19:33

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:58:40**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'Oral (ORAL)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Feb 2021 16:19:33

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:58:40**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Feb 2021 16:19:33

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '12 Feb 2021'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Feb 2021 16:19:33

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Feb 2021 16:19:33

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:58:40**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Feb 2021 16:19:33

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:58:40**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Feb 2021 16:19:33



US3312130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:58:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Feb 2021 16:19:33

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:58:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Feb 2021 16:19:33

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:58:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Feb 2021 16:19:33

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:58:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Feb 2021 16:19:33

US3312130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:58:40

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:26
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
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)	12 Mar 2021 09:40:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	12 Mar 2021 09:40:42
Data point term sent to Coder	System	11 Mar 2021 00:21:04
User entered 'aspirin'	Karol Moore (b) (4)	11 Mar 2021 00:20:42
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:58:40**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:26
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'No (N)'	(b) (4)	
	Karol Moore (b) (4)	11 Mar 2021 00:20:42
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:58:40**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:26
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'unstable angina'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Mar 2021 00:20:42

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:58:40**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:26
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '325' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:21:27
User entered '324'	Karol Moore (b) (4) (b) (4)	11 Mar 2021 00:20:42



**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:58:40**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:26
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'mg (mg)'	(b) (4)	
	Karol Moore (b) (4)	11 Mar 2021 00:20:42
	(b) (4)	

US3312130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:58:40

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:26
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4)	11 Mar 2021 00:20:42
	Karol Moore (b) (4)	
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:58:40**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:26
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'once daily (QD)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Mar 2021 00:20:42

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:58:40**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:26
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4)	
	Karol Moore (b) (4)	11 Mar 2021 00:20:42
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:58:40**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:26
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'Oral (ORAL)'	(b) (4) Karol Moore (b) (4) (b) (4)	11 Mar 2021 00:20:42

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:58:40**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:26
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4)	11 Mar 2021 00:20:42
	Karol Moore (b) (4)	
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:26
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '11 Feb 2021'	(b) (4)	
	Karol Moore (b) (4)	11 Mar 2021 00:20:42
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:26
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '0'	(b) (4)	
	Karol Moore (b) (4)	11 Mar 2021 00:20:42
	(b) (4)	



**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:58:40**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:26
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'No (N)'	(b) (4)	
	Karol Moore (b) (4)	11 Mar 2021 00:20:42
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:58:40**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:26
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '11 Feb 2021'	(b) (4)	
	Karol Moore (b) (4)	11 Mar 2021 00:20:42
	(b) (4)	

US3312130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:58:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:26
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'No (N)'	(b) (4)	
	Karol Moore (b) (4)	11 Mar 2021 00:20:42
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:58:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:26
User entered '1'	System	11 Mar 2021 00:20:42

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:58:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:26
User entered '1'	System	11 Mar 2021 00:20:42

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:58:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:26
User entered '804 (804)'	System	11 Mar 2021 00:20:42

US3312130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:58:40

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:29
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: VASODILATORS USED IN CARDIAC DISEASES, ATC: ORGANIC NITRATES, PRODUCT: GLYCERYL TRINITRATE, PRODUCTSYNONYM: NITROGLYCERIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	17 Mar 2021 11:49:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 11:49:44
Data point term sent to Coder	System	12 Mar 2021 00:14:07
User entered 'NITROGLYCERIN'	Karol Moore (b) (4) (b) (4)	12 Mar 2021 00:13:58

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:58:40**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:29
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'No (N)'	(b) (4)	
	Karol Moore (b) (4)	12 Mar 2021 00:13:58
	(b) (4)	



**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:58:40**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:29
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'UNSTABLE ANGINA'	(b) (4) Karol Moore (b) (4) (b) (4)	12 Mar 2021 00:13:58

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:58:40**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:29
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '0.4'	(b) (4)	
	Karol Moore (b) (4)	12 Mar 2021 00:13:58
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:58:40**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:29
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'mg (mg)'	(b) (4)	
	Karol Moore (b) (4)	12 Mar 2021 00:13:58
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:58:40**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:29
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4)	
	Karol Moore (b) (4)	12 Mar 2021 00:13:58
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:58:40**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:29
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'as needed (PRN)'	(b) (4)	
	Karol Moore (b) (4)	12 Mar 2021 00:13:58
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:58:40**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:29
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4)	12 Mar 2021 00:13:58
	Karol Moore (b) (4)	
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:58:40**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:29
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'Other (OTHER)'	(b) (4) Karol Moore (b) (4) (b) (4)	12 Mar 2021 00:13:58

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:58:40**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:29
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'SUBLINGUAL'	(b) (4) Karol Moore (b) (4) (b) (4)	12 Mar 2021 00:13:58



**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:29
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '11 Feb 2021'	(b) (4) Karol Moore (b) (4) (b) (4)	12 Mar 2021 00:13:58

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:29
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '0'	(b) (4)	
	Karol Moore (b) (4)	12 Mar 2021 00:13:58
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:58:40**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:29
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'No (N)'	(b) (4)	
	Karol Moore (b) (4)	12 Mar 2021 00:13:58
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:58:40**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:29
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '11 Feb 2021'	(b) (4) Karol Moore (b) (4) (b) (4)	12 Mar 2021 00:13:58

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:58:40**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:29
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'No (N)'	(b) (4)	
	Karol Moore (b) (4)	12 Mar 2021 00:13:58
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:58:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:29
User entered empty.	System	12 Mar 2021 00:13:58

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:58:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:29
User entered empty.	System	12 Mar 2021 00:13:58

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:58:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:29
User entered empty.	System	12 Mar 2021 00:13:58



US3312130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:58:40

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User closed query 'Per DM CLR: this Con Med was added/ had dose increased on 12 FEB 2021. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Mar 2021 11:09:47
Query 'Per DM CLR: this Con Med was added/ had dose increased on 12 FEB 2021. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' answered with 'correct as entered, medical history has end date' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 23:01:29
User opened query 'Per DM CLR: this Con Med was added/ had dose increased on 12 FEB 2021. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	21 Mar 2021 00:25:55
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT THROMBIN INHIBITORS, PRODUCT: BIVALIRUDIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 05:43:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 05:43:09
Data point term sent to Coder	System	12 Mar 2021 00:18:09

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 16:58:40**

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'bivalirudin'	Karol Moore (b) (4) (b) (4)	12 Mar 2021 00:17:09

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 16:58:40**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'No (N)'	(b) (4)	
	Karol Moore (b) (4)	12 Mar 2021 00:17:09
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 16:58:40**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'UNSTABLE ANGINA'	(b) (4) Karol Moore (b) (4) (b) (4)	12 Mar 2021 00:17:09

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 16:58:40**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'UNK'	(b) (4)	
	Karol Moore (b) (4)	12 Mar 2021 00:17:09
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 16:58:40**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'mg (mg)'	(b) (4) Karol Moore (b) (4) (b) (4)	12 Mar 2021 00:17:09

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 16:58:40**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4)	
	Karol Moore (b) (4)	12 Mar 2021 00:17:09
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 16:58:40**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'once (ONCE)'	(b) (4)	
	Karol Moore (b) (4)	12 Mar 2021 00:17:09
	(b) (4)	



**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 16:58:40**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4)	12 Mar 2021 00:17:09
	Karol Moore (b) (4)	
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 16:58:40**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	(b) (4) Karol Moore (b) (4) (b) (4)	12 Mar 2021 00:17:09

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 16:58:40**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4)	12 Mar 2021 00:17:09
	Karol Moore (b) (4)	
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '12 Feb 2021'	(b) (4)	
	Karol Moore (b) (4)	12 Mar 2021 00:17:09
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '0'	(b) (4)	
	Karol Moore (b) (4)	12 Mar 2021 00:17:09
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 16:58:40**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'No (N)'	(b) (4)	
	Karol Moore (b) (4)	12 Mar 2021 00:17:09
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 16:58:40**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '12 Feb 2021'	(b) (4)	
	Karol Moore (b) (4)	12 Mar 2021 00:17:09
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 16:58:40**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'No (N)'	(b) (4)	
	Karol Moore (b) (4)	12 Mar 2021 00:17:09
	(b) (4)	



**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 16:58:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:35
User entered empty.	System	12 Mar 2021 00:17:09

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 16:58:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:35
User entered empty.	System	12 Mar 2021 00:17:09

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 16:58:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:35
User entered empty.	System	12 Mar 2021 00:17:09

US3312130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:58:40

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	16 Mar 2021 12:01:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 12:01:49
Data point term sent to Coder	System	12 Mar 2021 00:18:08
User entered 'METOPROLOL'	Karol Moore (b) (4) (b) (4)	12 Mar 2021 00:17:53

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 16:58:40**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'No (N)'	(b) (4)	
	Karol Moore (b) (4)	12 Mar 2021 00:17:53
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 16:58:40**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'UNSTABLE ANGINA'	(b) (4) Karol Moore (b) (4) (b) (4)	12 Mar 2021 00:17:53

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 16:58:40**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '5'	(b) (4)	
	Karol Moore (b) (4)	12 Mar 2021 00:17:53
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 16:58:40**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'mg (mg)'	(b) (4)	
	Karol Moore (b) (4)	12 Mar 2021 00:17:53
	(b) (4)	



**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 16:58:40**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4)	12 Mar 2021 00:17:53
	Karol Moore (b) (4)	
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 16:58:40**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'as needed (PRN)'	(b) (4)	
	Karol Moore (b) (4)	12 Mar 2021 00:17:53
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 16:58:40**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4)	12 Mar 2021 00:17:53
	Karol Moore (b) (4)	
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 16:58:40**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Karol Moore (b) (4) (b) (4)	12 Mar 2021 00:17:53

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 16:58:40**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4)	12 Mar 2021 00:17:53
	Karol Moore (b) (4)	
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '11 Feb 2021'	(b) (4) Karol Moore (b) (4) (b) (4)	12 Mar 2021 00:17:53

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '0'	(b) (4)	
	Karol Moore (b) (4)	12 Mar 2021 00:17:53
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 16:58:40**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'No (N)'	(b) (4)	
	Karol Moore (b) (4)	12 Mar 2021 00:17:53
	(b) (4)	



**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 16:58:40**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '13 Feb 2021'	(b) (4)	
	Karol Moore (b) (4)	12 Mar 2021 00:17:53
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 16:58:40**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'No (N)'	(b) (4)	
	Karol Moore (b) (4)	12 Mar 2021 00:17:53
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 16:58:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:38
User entered empty.	System	12 Mar 2021 00:17:53

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 16:58:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:38
User entered empty.	System	12 Mar 2021 00:17:53

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 16:58:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:38
User entered empty.	System	12 Mar 2021 00:17:53

US3312130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:58:40

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:42
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: ANTIADRENERGIC AGENTS, CENTRALLY ACTING, ATC: IMIDAZOLINE RECEPTOR AGONISTS, PRODUCT: CLONIDINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	12 Mar 2021 10:26:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Mar 2021 10:26:43
Data point term sent to Coder	System	12 Mar 2021 00:19:10
User entered 'CLONIDINE'	Karol Moore (b) (4) (b) (4)	12 Mar 2021 00:18:29

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 16:58:40**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:42
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'No (N)'	(b) (4)	
	Karol Moore (b) (4)	12 Mar 2021 00:18:29
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 16:58:40**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:42
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'UNSTABLE ANGINA'	(b) (4) Karol Moore (b) (4) (b) (4)	12 Mar 2021 00:18:29



**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 16:58:40**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:42
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '0.2'	(b) (4)	
	Karol Moore (b) (4)	12 Mar 2021 00:18:29
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 16:58:40**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:42
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'mg (mg)'	(b) (4)	
	Karol Moore (b) (4)	12 Mar 2021 00:18:29
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 16:58:40**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:42
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4)	
	Karol Moore (b) (4)	12 Mar 2021 00:18:29
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 16:58:40**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:42
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'as needed (PRN)'	(b) (4)	
	Karol Moore (b) (4)	12 Mar 2021 00:18:29
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 16:58:40**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:42
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4)	
	Karol Moore (b) (4)	12 Mar 2021 00:18:29
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 16:58:40**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:42
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'Oral (ORAL)'	(b) (4) Karol Moore (b) (4) (b) (4)	12 Mar 2021 00:18:29

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 16:58:40**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:42
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4)	
	Karol Moore (b) (4)	12 Mar 2021 00:18:29
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:42
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '11 Feb 2021'	(b) (4)	
	Karol Moore (b) (4)	12 Mar 2021 00:18:29
	(b) (4)	



**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:42
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '0'	(b) (4)	
	Karol Moore (b) (4)	12 Mar 2021 00:18:29
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 16:58:40**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:42
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'No (N)'	(b) (4)	
	Karol Moore (b) (4)	12 Mar 2021 00:18:29
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 16:58:40**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:42
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '13 Feb 2021'	(b) (4)	
	Karol Moore (b) (4)	12 Mar 2021 00:18:29
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 16:58:40**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:42
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'No (N)'	(b) (4)	
	Karol Moore (b) (4)	12 Mar 2021 00:18:29
	(b) (4)	

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 16:58:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:42
User entered empty.	System	12 Mar 2021 00:18:29

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 16:58:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:42
User entered empty.	System	12 Mar 2021 00:18:29

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 16:58:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:42
User entered empty.	System	12 Mar 2021 00:18:29

US3312130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:58:40

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Apr 2021 18:25:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 18:25:44
Data point term sent to Coder	System	08 Apr 2021 18:25:05
User entered 'LISINOPRIL'	(b) (4), (b) (6)	08 Apr 2021 18:24:03



**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 16:58:40**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:24:03

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 16:58:40**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'HYPERTENTION'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:24:03

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 16:58:40**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '40'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:24:03

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 16:58:40**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:24:03

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 16:58:40**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:24:03

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 16:58:40**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:24:03

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 16:58:40**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:24:03

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 16:58:40**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:24:03



**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 16:58:40**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:24:03

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '11 Feb 2021'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:24:03

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:24:03

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 16:58:40**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:24:03

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 16:58:40**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:24:03

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 16:58:40**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:24:03

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 16:58:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Apr 2021 18:24:03

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 16:58:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Apr 2021 18:24:03



**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 16:58:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Apr 2021 18:24:03

US3312130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:58:40

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:51
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, PRODUCT: PROMETHAZINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	09 Apr 2021 04:36:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 04:36:36
Data point term sent to Coder	System	08 Apr 2021 18:31:15
User entered 'PROMETHAZINE'	(b) (4), (b) (6)	08 Apr 2021 18:31:02

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 16:58:40**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:51
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:31:02

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 16:58:40**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:51
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'UNSTABLE ANGINA'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:31:02

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 16:58:40**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:51
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '12.5'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:31:02

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 16:58:40**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:51
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:31:02

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 16:58:40**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:51
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:31:02

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 16:58:40**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:51
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:31:02



**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 16:58:40**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:51
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:31:02

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 16:58:40**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:51
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:31:02

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 16:58:40**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:51
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:31:02

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:51
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '11 Feb 2021'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:31:02

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:51
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:31:02

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 16:58:40**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:51
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:31:02

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 16:58:40**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:51
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '13 Feb 2021'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:31:02

US3312130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:58:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:51
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:31:02



**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 16:58:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:51
User entered empty.	System	08 Apr 2021 18:31:02

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 16:58:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:51
User entered empty.	System	08 Apr 2021 18:31:02

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 16:58:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:51
User entered empty.	System	08 Apr 2021 18:31:02

US3312130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:58:40

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, PRODUCT: PROMETHAZINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	09 Apr 2021 04:36:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 04:36:38
Data point term sent to Coder	System	08 Apr 2021 18:32:16
User entered 'PROMETHAZINE'	(b) (4), (b) (6)	08 Apr 2021 18:32:03

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 16:58:40**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:32:03

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 16:58:40**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'UNSTABLE ANGINA'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:32:03

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 16:58:40**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '25'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:32:03

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 16:58:40**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:32:03



**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 16:58:40**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:32:03

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 16:58:40**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:32:03

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 16:58:40**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:32:03

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 16:58:40**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:32:03

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 16:58:40**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:32:03

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '11 Feb 2021'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:32:03

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:32:03

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 16:58:40**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:32:03



**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 16:58:40**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '13 Feb 2021'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:32:03

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 16:58:40**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:32:03

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 16:58:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:54
User entered empty.	System	08 Apr 2021 18:32:03

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 16:58:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:54
User entered empty.	System	08 Apr 2021 18:32:03

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 16:58:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:54
User entered empty.	System	08 Apr 2021 18:32:03

US3312130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:58:40

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Apr 2021 04:19:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Apr 2021 04:19:37
Data point term sent to Coder	System	08 Apr 2021 18:33:19
User entered 'ONDANSETRON'	(b) (4), (b) (6)	08 Apr 2021 18:33:00

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 16:58:40**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:33:00

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 16:58:40**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'UNSTABLE ANGINA'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:33:00



**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 16:58:40**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '4'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:33:00

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 16:58:40**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:33:00

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 16:58:40**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:33:00

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 16:58:40**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:33:00

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 16:58:40**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:33:00

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 16:58:40**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:33:00

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 16:58:40**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:33:00

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '11 Feb 2021'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:33:00



**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:33:00

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 16:58:40**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:33:00

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 16:58:40**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '13 Feb 2021'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:33:00

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 16:58:40**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:33:00

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 16:58:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:57
User entered empty.	System	08 Apr 2021 18:33:00

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 16:58:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:57
User entered empty.	System	08 Apr 2021 18:33:00

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 16:58:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:57
User entered empty.	System	08 Apr 2021 18:33:00

US3312130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:58:40

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES, PRODUCT: LIRAGLUTIDE, PRODUCTSYNONYM: VICTOZA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 18:36:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 18:36:54
Data point term sent to Coder	System	08 Apr 2021 18:36:23
Data point term sent to Coder	System	08 Apr 2021 18:35:21
User entered 'VICTOZA'	(b) (4), (b) (6)	08 Apr 2021 18:35:00



**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 16:58:40**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:35:00

US3312130

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:58:40

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'DIABETES MELLITUS TYPE II'	(b) (4)	08 Apr 2021 18:35:33
reason for change: Data Entry Error	(b) (4), (b) (6)	
User entered 'DIABETES'	(b) (4), (b) (6)	08 Apr 2021 18:35:00

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 16:58:40**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '0.6'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:35:00

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 16:58:40**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:35:00

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 16:58:40**

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:35:00

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 16:58:40**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:35:00

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 16:58:40**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:35:00

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 16:58:40**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:35:00



**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 16:58:40**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:35:00

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '10 Mar 2021'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:35:00

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 16:58:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:35:00

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 16:58:40**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:35:00

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 16:58:40**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:35:00

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 16:58:40**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:21
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 16:55:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:35:00

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 16:58:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Apr 2021 18:35:00

**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 16:58:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Apr 2021 18:35:00



**US3312130**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 16:58:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Apr 2021 18:35:00

**US3312130**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 09 Jun 2021 16:58:40**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:25:47
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:47:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	23 Feb 2021 16:19:42
User entered 'No (N)'	Karol Moore (b) (4)	18 Feb 2021 16:28:36
	(b) (4), (b) (6)	

US3312130

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:58:40

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:48:06
User closed query 'Per ETRTR: Procedure was performed on 12Feb21 related to SAE "Angina". Please go to SAE page and tick within "Concomitant Procedures" Action taken checkbox. thanks!' (Site from CRA). User signature succeeded.	(b) (4), (b) (6)	19 Apr 2021 20:48:04
	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
	(b) (4)	
Query 'Per ETRTR: Procedure was performed on 12Feb21 related to SAE "Angina". Please go to SAE page and tick within "Concomitant Procedures" Action taken checkbox. thanks!' answered with 'UPDATED' (Site from CRA).	Karol Moore (b) (4)	18 Mar 2021 15:39:58
	(b) (4)	
User opened query 'Per ETRTR: Procedure was performed on 12Feb21 related to SAE "Angina". Please go to SAE page and tick within "Concomitant Procedures" Action taken checkbox. thanks!' (Site from CRA).	(b) (4), (b) (6)	03 Mar 2021 04:50:52
User entered '12 Feb 2021'	Karol Moore (b) (4)	23 Feb 2021 16:20:03
	(b) (4)	

**US3312130**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:48:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'coronary stent placement'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Feb 2021 16:20:03

**US3312130**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:48:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'Adverse Event (AE)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Feb 2021 16:20:03

**US3312130**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 09 Jun 2021 16:58:40**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:48:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Feb 2021 16:20:03

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'USA-US300-2020-MRNA-1273-P301000022'	System	18 Dec 2020 18:46:17

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'Yes (Y)'	System	18 Dec 2020 18:46:17



**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'No (N)'	System	18 Dec 2020 18:46:17

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'No (N)'	System	18 Dec 2020 18:46:17

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'Yes (Y)'	System	18 Dec 2020 18:46:17

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'No (N)'	System	18 Dec 2020 18:46:17

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'No (N)'	System	18 Dec 2020 18:46:17

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'No (N)'	System	18 Dec 2020 18:46:17

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'Carlos'	System	18 Dec 2020 18:46:17

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'Fierro'	System	18 Dec 2020 18:46:17



**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered '16300 College Blvd'	System	18 Dec 2020 18:46:17

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'Shawnee'	System	18 Dec 2020 18:46:17

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'KS'	System	18 Dec 2020 18:46:17

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered '66219'	System	18 Dec 2020 18:46:17

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'US'	System	18 Dec 2020 18:47:01

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	09 Apr 2021 14:45:22
User entered '4'	System	18 Feb 2021 15:53:05
User entered '3'	System	22 Jan 2021 17:05:21
User entered '2'	System	22 Dec 2020 19:51:46
User entered '1'	System	18 Dec 2020 18:47:01

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'USA-US300-2020-MRNA-1273-P301000022'	System	18 Dec 2020 18:46:17

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'Yes (Y)'	System	18 Dec 2020 18:46:17



**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'No (N)'	System	18 Dec 2020 18:46:17

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'No (N)'	System	18 Dec 2020 18:46:17

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'Yes (Y)'	System	18 Dec 2020 18:46:17

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'No (N)'	System	18 Dec 2020 18:46:17

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'No (N)'	System	18 Dec 2020 18:46:17

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'No (N)'	System	18 Dec 2020 18:46:17

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'Carlos'	System	18 Dec 2020 18:46:17

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'Fierro'	System	18 Dec 2020 18:46:17



**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered '16300 College Blvd'	System	18 Dec 2020 18:46:17

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'Shawnee'	System	18 Dec 2020 18:46:17

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'KS'	System	18 Dec 2020 18:46:17

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered '66219'	System	18 Dec 2020 18:46:17

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'US'	System	18 Dec 2020 18:47:01

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	09 Apr 2021 14:45:22
User entered '4'	System	18 Feb 2021 15:53:05
User entered '3'	System	22 Jan 2021 17:05:21
User entered '2'	System	22 Dec 2020 19:51:46
User entered '1'	System	18 Dec 2020 18:47:01

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '18/Dec/2020 13:47'	(b) (4) System	18 Dec 2020 18:47:01

US3312130

Folder: SAE USA-US300-2020-MRNA-1273-P301000022

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:58:40

**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.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 18:47:09
User entered 'I'	(b) (4), (b) (6)	18 Dec 2020 18:47:01



**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'USA-US300-2020-MRNA-1273-P301000022'	System	18 Dec 2020 18:46:17

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Serious](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'Yes (Y)'	System	18 Dec 2020 18:46:17

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'No (N)'	System	18 Dec 2020 18:46:17

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'No (N)'	System	18 Dec 2020 18:46:17

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'Yes (Y)'	System	18 Dec 2020 18:46:17

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'No (N)'	System	18 Dec 2020 18:46:17

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'No (N)'	System	18 Dec 2020 18:46:17

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'No (N)'	System	18 Dec 2020 18:46:17



**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'Carlos'	System	18 Dec 2020 18:46:17

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'Fierro'	System	18 Dec 2020 18:46:17

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered '16300 College Blvd'	System	18 Dec 2020 18:46:17

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'Shawnee'	System	18 Dec 2020 18:46:17

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'KS'	System	18 Dec 2020 18:46:17

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered '66219'	System	18 Dec 2020 18:46:17

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'US'	System	18 Dec 2020 18:47:01

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	09 Apr 2021 14:45:22
User entered '4'	System	18 Feb 2021 15:53:05
User entered '3'	System	22 Jan 2021 17:05:21
User entered '2'	System	22 Dec 2020 19:51:46
User entered '1'	System	18 Dec 2020 18:47:01



**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '22/Dec/2020 19:51'	(b) (4) System	22 Dec 2020 19:51:46

US3312130

Folder: SAE USA-US300-2020-MRNA-1273-P301000022

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:58:40

**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.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:05:00
User entered 'I'	(b) (4), (b) (6)	22 Dec 2020 19:51:46

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'USA-US300-2020-MRNA-1273-P301000022'	System	18 Dec 2020 18:46:17

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'Yes (Y)'	System	18 Dec 2020 18:46:17

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'No (N)'	System	18 Dec 2020 18:46:17

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'No (N)'	System	18 Dec 2020 18:46:17

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'Yes (Y)'	System	18 Dec 2020 18:46:17

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'No (N)'	System	18 Dec 2020 18:46:17



**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'No (N)'	System	18 Dec 2020 18:46:17

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'No (N)'	System	18 Dec 2020 18:46:17

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'Carlos'	System	18 Dec 2020 18:46:17

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'Fierro'	System	18 Dec 2020 18:46:17

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered '16300 College Blvd'	System	18 Dec 2020 18:46:17

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'Shawnee'	System	18 Dec 2020 18:46:17

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'KS'	System	18 Dec 2020 18:46:17

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered '66219'	System	18 Dec 2020 18:46:17



**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'US'	System	18 Dec 2020 18:47:01

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	09 Apr 2021 14:45:22
User entered '4'	System	18 Feb 2021 15:53:05
User entered '3'	System	22 Jan 2021 17:05:21
User entered '2'	System	22 Dec 2020 19:51:46
User entered '1'	System	18 Dec 2020 18:47:01

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 16:58:40**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '22/Jan/2021 12:05'	(b) (4) System	22 Jan 2021 17:05:21

US3312130

Folder: SAE USA-US300-2020-MRNA-1273-P301000022

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:58:40

**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.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 15:52:42
User entered 'I'	(b) (4), (b) (6)	22 Jan 2021 17:05:21

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'USA-US300-2020-MRNA-1273-P301000022'	System	18 Dec 2020 18:46:17

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'Yes (Y)'	System	18 Dec 2020 18:46:17

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'No (N)'	System	18 Dec 2020 18:46:17

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'No (N)'	System	18 Dec 2020 18:46:17



**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'Yes (Y)'	System	18 Dec 2020 18:46:17

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'No (N)'	System	18 Dec 2020 18:46:17

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'No (N)'	System	18 Dec 2020 18:46:17

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'No (N)'	System	18 Dec 2020 18:46:17

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'Carlos'	System	18 Dec 2020 18:46:17

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'Fierro'	System	18 Dec 2020 18:46:17

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered '16300 College Blvd'	System	18 Dec 2020 18:46:17

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'Shawnee'	System	18 Dec 2020 18:46:17



**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'KS'	System	18 Dec 2020 18:46:17

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered '66219'	System	18 Dec 2020 18:46:17

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'US'	System	18 Dec 2020 18:47:01

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	09 Apr 2021 14:45:22
User entered '4'	System	18 Feb 2021 15:53:05
User entered '3'	System	22 Jan 2021 17:05:21
User entered '2'	System	22 Dec 2020 19:51:46
User entered '1'	System	18 Dec 2020 18:47:01

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form (4)**

**Generated On: 09 Jun 2021 16:58:40**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '18/Feb/2021 10:53'	(b) (4) System	18 Feb 2021 15:53:05

US3312130

Folder: SAE USA-US300-2020-MRNA-1273-P301000022

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:58:40

**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.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:44:56
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered 'I'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 15:53:05

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'USA-US300-2020-MRNA-1273-P301000022'	System	18 Dec 2020 18:46:17

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'Yes (Y)'	System	18 Dec 2020 18:46:17



**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'No (N)'	System	18 Dec 2020 18:46:17

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'No (N)'	System	18 Dec 2020 18:46:17

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'Yes (Y)'	System	18 Dec 2020 18:46:17

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'No (N)'	System	18 Dec 2020 18:46:17

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'No (N)'	System	18 Dec 2020 18:46:17

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'No (N)'	System	18 Dec 2020 18:46:17

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'Carlos'	System	18 Dec 2020 18:46:17

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'Fierro'	System	18 Dec 2020 18:46:17



**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered '16300 College Blvd'	System	18 Dec 2020 18:46:17

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'Shawnee'	System	18 Dec 2020 18:46:17

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'KS'	System	18 Dec 2020 18:46:17

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered '66219'	System	18 Dec 2020 18:46:17

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:51:34
User entered 'US'	System	18 Dec 2020 18:47:01

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	09 Apr 2021 14:45:22
User entered '4'	System	18 Feb 2021 15:53:05
User entered '3'	System	22 Jan 2021 17:05:21
User entered '2'	System	22 Dec 2020 19:51:46
User entered '1'	System	18 Dec 2020 18:47:01

**US3312130**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000022**

**Form: Safety Report Form (5)**

**Generated On: 09 Jun 2021 16:58:40**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:57:39
User entered '09/Apr/2021 10:45'	(b) (4) System	09 Apr 2021 14:45:22

US3312130

Folder: SAE USA-US300-2020-MRNA-1273-P301000022

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:58:40

**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.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:36
User signature succeeded.	Carlos Fierro (b) (4)	09 Apr 2021 15:57:39
User entered 'I'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:45:22



**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'USA-US300-2021-MRNA-1273-P301000015'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'Yes (Y)'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'No (N)'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'No (N)'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'Yes (Y)'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'No (N)'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'No (N)'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'No (N)'	System	18 Feb 2021 17:55:13



**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'Carlos'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'Fierro'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered '16300 College Blvd'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'Shawnee'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'KS'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered '66219'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:30:16
User entered 'US'	System	18 Feb 2021 17:55:42

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	19 Mar 2021 12:53:12
User entered '5'	System	18 Mar 2021 14:22:35
User entered '4'	System	11 Mar 2021 12:46:56
User entered '3'	System	10 Mar 2021 14:56:12
User entered '2'	System	08 Mar 2021 16:30:31
User entered '1'	System	18 Feb 2021 17:55:42



**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'USA-US300-2021-MRNA-1273-P301000015'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'Yes (Y)'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'No (N)'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'No (N)'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'Yes (Y)'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'No (N)'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'No (N)'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'No (N)'	System	18 Feb 2021 17:55:13



**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'Carlos'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'Fierro'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered '16300 College Blvd'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'Shawnee'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'KS'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered '66219'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:30:16
User entered 'US'	System	18 Feb 2021 17:55:42

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	19 Mar 2021 12:53:12
User entered '5'	System	18 Mar 2021 14:22:35
User entered '4'	System	11 Mar 2021 12:46:56
User entered '3'	System	10 Mar 2021 14:56:12
User entered '2'	System	08 Mar 2021 16:30:31
User entered '1'	System	18 Feb 2021 17:55:42



**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 16:58:40**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '18/Feb/2021 12:55'	(b) (4) System	18 Feb 2021 17:55:42

US3312130

Folder: SAE USA-US300-2021-MRNA-1273-P301000015

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:58:40

**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.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:30:16
User entered 'I'	(b) (4), (b) (6)	18 Feb 2021 17:55:42

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'USA-US300-2021-MRNA-1273-P301000015'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'Yes (Y)'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'No (N)'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'No (N)'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'Yes (Y)'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'No (N)'	System	18 Feb 2021 17:55:13



**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'No (N)'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'No (N)'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'Carlos'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'Fierro'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered '16300 College Blvd'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'Shawnee'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'KS'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered '66219'	System	18 Feb 2021 17:55:13



**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:30:16
User entered 'US'	System	18 Feb 2021 17:55:42

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	19 Mar 2021 12:53:12
User entered '5'	System	18 Mar 2021 14:22:35
User entered '4'	System	11 Mar 2021 12:46:56
User entered '3'	System	10 Mar 2021 14:56:12
User entered '2'	System	08 Mar 2021 16:30:31
User entered '1'	System	18 Feb 2021 17:55:42

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 16:58:40**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '08/Mar/2021 11:30'	(b) (4) System	08 Mar 2021 16:30:31

US3312130

Folder: SAE USA-US300-2021-MRNA-1273-P301000015

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:58:40

**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.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 14:55:19
User entered 'I'	(b) (4), (b) (6)	08 Mar 2021 16:30:31

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'USA-US300-2021-MRNA-1273-P301000015'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'Yes (Y)'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'No (N)'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'No (N)'	System	18 Feb 2021 17:55:13



**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'Yes (Y)'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'No (N)'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'No (N)'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'No (N)'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'Carlos'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'Fierro'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered '16300 College Blvd'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'Shawnee'	System	18 Feb 2021 17:55:13



**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'KS'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered '66219'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:30:16
User entered 'US'	System	18 Feb 2021 17:55:42

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	19 Mar 2021 12:53:12
User entered '5'	System	18 Mar 2021 14:22:35
User entered '4'	System	11 Mar 2021 12:46:56
User entered '3'	System	10 Mar 2021 14:56:12
User entered '2'	System	08 Mar 2021 16:30:31
User entered '1'	System	18 Feb 2021 17:55:42

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 16:58:40**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '10/Mar/2021 09:55'	(b) (4) System	10 Mar 2021 14:56:12

US3312130

Folder: SAE USA-US300-2021-MRNA-1273-P301000015

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:58:40

**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.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 12:46:36
User entered 'I'	(b) (4), (b) (6)	10 Mar 2021 14:56:12

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'USA-US300-2021-MRNA-1273-P301000015'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'Yes (Y)'	System	18 Feb 2021 17:55:13



**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'No (N)'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'No (N)'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'Yes (Y)'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'No (N)'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'No (N)'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'No (N)'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'Carlos'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'Fierro'	System	18 Feb 2021 17:55:13



**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered '16300 College Blvd'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'Shawnee'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'KS'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered '66219'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:30:16
User entered 'US'	System	18 Feb 2021 17:55:42

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	19 Mar 2021 12:53:12
User entered '5'	System	18 Mar 2021 14:22:35
User entered '4'	System	11 Mar 2021 12:46:56
User entered '3'	System	10 Mar 2021 14:56:12
User entered '2'	System	08 Mar 2021 16:30:31
User entered '1'	System	18 Feb 2021 17:55:42

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form (4)**

**Generated On: 09 Jun 2021 16:58:40**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '11/Mar/2021 07:46'	(b) (4) System	11 Mar 2021 12:46:56

US3312130

Folder: SAE USA-US300-2021-MRNA-1273-P301000015

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:58:40

**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.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 14:22:23
User entered 'I'	(b) (4), (b) (6)	11 Mar 2021 12:46:56



**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'USA-US300-2021-MRNA-1273-P301000015'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'Yes (Y)'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'No (N)'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'No (N)'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'Yes (Y)'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'No (N)'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'No (N)'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'No (N)'	System	18 Feb 2021 17:55:13



**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'Carlos'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'Fierro'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered '16300 College Blvd'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'Shawnee'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'KS'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered '66219'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:30:16
User entered 'US'	System	18 Feb 2021 17:55:42

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	19 Mar 2021 12:53:12
User entered '5'	System	18 Mar 2021 14:22:35
User entered '4'	System	11 Mar 2021 12:46:56
User entered '3'	System	10 Mar 2021 14:56:12
User entered '2'	System	08 Mar 2021 16:30:31
User entered '1'	System	18 Feb 2021 17:55:42



**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form (5)**

**Generated On: 09 Jun 2021 16:58:40**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '18/Mar/2021 10:22'	(b) (4) System	18 Mar 2021 14:22:35

US3312130

Folder: SAE USA-US300-2021-MRNA-1273-P301000015

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:58:40

**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.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 12:52:51
User entered 'I'	(b) (4), (b) (6)	18 Mar 2021 14:22:35

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'USA-US300-2021-MRNA-1273-P301000015'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'Yes (Y)'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'No (N)'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'No (N)'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'Yes (Y)'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'No (N)'	System	18 Feb 2021 17:55:13



**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'No (N)'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'No (N)'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'Carlos'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'Fierro'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered '16300 College Blvd'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'Shawnee'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered 'KS'	System	18 Feb 2021 17:55:13

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:55:30
User entered '66219'	System	18 Feb 2021 17:55:13



**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:30:16
User entered 'US'	System	18 Feb 2021 17:55:42

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:58:40**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	19 Mar 2021 12:53:12
User entered '5'	System	18 Mar 2021 14:22:35
User entered '4'	System	11 Mar 2021 12:46:56
User entered '3'	System	10 Mar 2021 14:56:12
User entered '2'	System	08 Mar 2021 16:30:31
User entered '1'	System	18 Feb 2021 17:55:42

**US3312130**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000015**

**Form: Safety Report Form (6)**

**Generated On: 09 Jun 2021 16:58:40**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
User entered '19/Mar/2021 08:53'	(b) (4) System	19 Mar 2021 12:53:12

US3312130

Folder: SAE USA-US300-2021-MRNA-1273-P301000015

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 16:58:40

**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.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:42:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 18:16:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:42:56
User entered 'I'	(b) (4), (b) (6)	19 Mar 2021 12:53:12