

US3312637 (Prod: Johnson County Clin-Trials)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:06:05

All time stamps listed in this document are displayed in GMT

US3312637

Form: Participant Creation

Data signed: (b) (4) 08 Apr 2021 15:19:40

Generated On: 09 Jun 2021 17:06:05

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Participant ID

US3312637

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

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US3312637

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 15:19:47

Generated On: 09 Jun 2021 17:06:05

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 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	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 08 Apr 2021 15:19:46

Generated On: 09 Jun 2021 17:06:05

Date of Birth (MMM yyyy)	(b) (6) 1962
Age	57
Age Units	YEARS
Age (Derived)	57
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	True
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) 08 Apr 2021 15:19:46

Generated On: 09 Jun 2021 17:06:05

Date of Informed Consent ( <i>dd MMM yyyy</i> )	11 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input checked="" 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) 08 Apr 2021 15:19:46

Generated On: 09 Jun 2021 17:06:05

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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) 08 Apr 2021 15:19:47

Generated On: 09 Jun 2021 17:06:05

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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 15:19:47

Generated On: 09 Jun 2021 17:06:05

Condition	SARCOIDOSIS
Start date (dd MMM yyyy)	UN UNK 1986
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 1986
Start Year (derived)	1986
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 15:19:47

Generated On: 09 Jun 2021 17:06:05

Condition	GASTROESOPHAGEAL REFLUX DISEASE
Start date (dd MMM yyyy)	UN UNK 2001
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 2001
Start Year (derived)	2001
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 15:19:47

Generated On: 09 Jun 2021 17:06:05

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 2001
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 2001
Start Year (derived)	2001
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 15:19:47

Generated On: 09 Jun 2021 17:06:05

Condition	L4-L5 BULGING DISC
Start date (dd MMM yyyy)	06 SEP 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)	06 SEP 2017
Stop date completely unknown	False
Start Month and Year (derived)	SEP 2017
Start Year (derived)	2017
Stop Month and Year (derived)	SEP 2017
Stop Year (derived)	2017

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 08 Apr 2021 15:19:47

Generated On: 09 Jun 2021 17:06:05

Condition	LEFT HUMEROUS COMPOUND FRACTURE
Start date (dd MMM yyyy)	06 SEP 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)	06 SEP 2017
Stop date completely unknown	False
Start Month and Year (derived)	SEP 2017
Start Year (derived)	2017
Stop Month and Year (derived)	SEP 2017
Stop Year (derived)	2017

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 08 Apr 2021 15:19:47

Generated On: 09 Jun 2021 17:06:05

Condition	LEFT HUMEROUS COMPOUND FRACTURE SURGICAL REPAIR
Start date (dd MMM yyyy)	06 SEP 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)	06 SEP 2017
Stop date completely unknown	False
Start Month and Year (derived)	SEP 2017
Start Year (derived)	2017
Stop Month and Year (derived)	SEP 2017
Stop Year (derived)	2017

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 08 Apr 2021 15:19:47

Generated On: 09 Jun 2021 17:06:05

Condition	CHOLECYSTECTOMY
Start date (dd MMM yyyy)	UN UNK 2001
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 2001
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2001
Start Year (derived)	2001
Stop Month and Year (derived)	JAN 2001
Stop Year (derived)	2001

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 08 Apr 2021 15:19:47

Generated On: 09 Jun 2021 17:06:05

Condition	CHOLELITHIASIS
Start date (dd MMM yyyy)	UN UNK 2001
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 2001
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2001
Start Year (derived)	2001
Stop Month and Year (derived)	JAN 2001
Stop Year (derived)	2001

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 08 Apr 2021 15:19:47

Generated On: 09 Jun 2021 17:06:05

Condition	SLEEP APNEA
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 (10)

Data signed: (b) (4) 08 Apr 2021 15:19:47

Generated On: 09 Jun 2021 17:06:05

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

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 08 Apr 2021 15:19:47

Generated On: 09 Jun 2021 17:06:05

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

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 08 Apr 2021 15:19:47

Generated On: 09 Jun 2021 17:06:05

Condition	HYPERTENSION
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 (13)

Data signed: (b) (4) 08 Apr 2021 15:19:47

Generated On: 09 Jun 2021 17:06:05

Condition	SUPRAVENTRICULAR TACHYCARDIA
Start date (dd MMM yyyy)	UN UNK 1980
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1980
Start Year (derived)	1980
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 08 Apr 2021 15:19:47

Generated On: 09 Jun 2021 17:06:05

Condition	ANGINA
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 08 Apr 2021 15:19:47

Generated On: 09 Jun 2021 17:06:05

Condition	SCIATICA
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 (16)

Data signed: (b) (4) 08 Apr 2021 15:19:47

Generated On: 09 Jun 2021 17:06:05

Condition	LOW BACK PAIN
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 (17)

Data signed: (b) (4) 08 Apr 2021 15:19:47

Generated On: 09 Jun 2021 17:06:05

Condition	DIFFICULTY SLEEPING
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 (18)

Data signed: (b) (4) 08 Apr 2021 15:19:47

Generated On: 09 Jun 2021 17:06:05

Condition	CORONARY ARTERY DISEASE
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 08 Apr 2021 15:19:48

Generated On: 09 Jun 2021 17:06:05

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 SEP 2020
Time of assessment (00:00-23:59)	14:07 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 14:07
Height (xxx.x)	69 in
Weight (xxx.x)	233 lb
BMI (xxx.x)	34.48003 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 15:19:47

Generated On: 09 Jun 2021 17:06:05

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 SEP 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) 08 Apr 2021 15:19:47

Generated On: 09 Jun 2021 17:06:05

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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) 08 Apr 2021 15:19:47

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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)	True
<b>Resides in low density, multi-family setting without</b> (e.g., apartments complex without shared entrances or elevators, duplexes)	False
<b>Resides in a single family home</b> (i.e., detached housing)	False
<b>Other</b>	False
<b>Specify</b>	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 15:20:05

Generated On: 09 Jun 2021 17:06:05

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 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	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 08 Apr 2021 15:20:04

Generated On: 09 Jun 2021 17:06:05

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

What was the participant's randomization number? 146256

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) 08 Apr 2021 15:20:05

Generated On: 09 Jun 2021 17:06:05

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) 08 Apr 2021 15:20:05

Generated On: 09 Jun 2021 17:06:05

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 SEP 2020
Time of assessment (00:00-23:59)	14:07 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 14:07
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)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 08 Apr 2021 15:20:05

Generated On: 09 Jun 2021 17:06:05

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 SEP 2020
Time of assessment (00:00-23:59)	16:06 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 16:06
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)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 15:20:04

Generated On: 09 Jun 2021 17:06:05

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) 08 Apr 2021 15:20:03

Generated On: 09 Jun 2021 17:06:05

Was study treatment given? Yes ☒  
No ☐

If No, reason not given

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 15:35 (24 HR)

Treatment Date and Time (derived) 11 SEP 2020 15:35

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) 08 Apr 2021 15:20:04

Generated On: 09 Jun 2021 17:06:05

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

11 SEP 2020

Collection time (00:00-23:59)

14:59 (24 HR)

Collection date and time (derived)

11 SEP 2020 14:59

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 08 Apr 2021 15:19:48

Generated On: 09 Jun 2021 17:06:05

Collection date (dd MMM yyyy)			11 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:51	11 SEP 2020 14:51
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 15:20:03

Generated On: 09 Jun 2021 17:06:05

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 17:06:05

**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

98.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 SEP 2020 16:09

PC Open Date & Time

11 SEP 2020 15:55

PC Close Date & Time

11 SEP 2020 18:25



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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:06:05

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.1 °F

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

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

PC Time Stamp	11 SEP 2020 23:12
PC Open Date & Time	11 SEP 2020 19:20
PC Close Date & Time	12 SEP 2020 11:59

US3312637

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:06:05

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 15:36

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3312637

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:06:05

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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

98.3 °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

13 SEP 2020 20:59

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3312637

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:06:05

**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

14 SEP 2020 13:20

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3312637

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:06:05

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °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

15 SEP 2020 12:09

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3312637

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:06:05

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °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

16 SEP 2020 13:05

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3312637

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:06:05

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 18:33

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3312637

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:06:05

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

11 SEP 2020 16:09

PC Open Date & Time

11 SEP 2020 15:55

PC Close Date & Time

11 SEP 2020 18:25



US3312637

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:06:05

**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

11 SEP 2020 23:13

PC Open Date & Time

11 SEP 2020 19:20

PC Close Date & Time

12 SEP 2020 11:59

US3312637

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:06:05

**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

12 SEP 2020 15:36

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3312637

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:06:05

**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

13 SEP 2020 20:59

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3312637

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:06:05

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

14 SEP 2020 13:20

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3312637

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:06:05

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

15 SEP 2020 12:09

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3312637

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:06:05

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

16 SEP 2020 13:05

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3312637

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:06:05

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

17 SEP 2020 18:33

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:06:05

**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 ☐



US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:06:05

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 16:10
PC Open Date & Time	11 SEP 2020 15:55
PC Close Date & Time	11 SEP 2020 18:25

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:06:05

**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 ☐

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:06:05

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 23:13
PC Open Date & Time	11 SEP 2020 19:20
PC Close Date & Time	12 SEP 2020 11:59

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:06:05

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:06:05

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 15:37
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:06:05

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)

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:06:05

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 21:00
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:06:05

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:06:05

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 13:21
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:06:05

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:06:05

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 12:10
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:06:05

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)

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:06:05

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 13:06
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:06:05

**TIMEPOINT**

**DAY 7**

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:06:05

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 18:34
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3312637

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 15:19:46

Generated On: 09 Jun 2021 17:06:05

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 18 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*



US3312637

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 15:19:46

Generated On: 09 Jun 2021 17:06:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312637

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 15:19:45

Generated On: 09 Jun 2021 17:06:05

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*

US3312637

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 15:19:45

Generated On: 09 Jun 2021 17:06:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312637

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 15:19:45

Generated On: 09 Jun 2021 17:06:05

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*

US3312637

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 15:19:45

Generated On: 09 Jun 2021 17:06:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312637

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 15:20:08

Generated On: 09 Jun 2021 17:06:05

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	09 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	VISIT2

US3312637

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 08 Apr 2021 15:20:08

Generated On: 09 Jun 2021 17:06:05

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)	09 OCT 2020
Time of assessment (00:00-23:59)	10:40 (24 HR)
Vital Signs Date and Time (derived)	09 OCT 2020 10:40
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)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG

US3312637

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 08 Apr 2021 15:20:08

Generated On: 09 Jun 2021 17:06:05

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
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 <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
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	



US3312637

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 15:20:08

Generated On: 09 Jun 2021 17:06:05

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

09 OCT 2020

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

US3312637

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 08 Apr 2021 15:20:08

Generated On: 09 Jun 2021 17:06:05

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

IP INITIALLY WITHHELD WITH POSSIBLE DOSING AT A LATER DATE, BUT DUE TO SAE DEVELOPMENT (STENT PLACEMENT NOT KNOWN INITIALLY). IP WITHHELD FOR SUBJECT SAFETY

What was the study treatment? \_\_\_\_\_

What was the treatment date? (dd MMM yyyy) \_\_\_\_\_

What was the treatment time? (00:00-23:59) \_\_\_\_\_

Treatment Date and Time (derived) \_\_\_\_\_

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

What was the frequency of the study treatment dosing? \_\_\_\_\_

What was the route of administration for the study treatment? \_\_\_\_\_

US3312637

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Apr 2021 15:20:08

Generated On: 09 Jun 2021 17:06:05

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3312637

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 08 Apr 2021 15:20:08

Generated On: 09 Jun 2021 17:06:05

Collection date (*dd MMM yyyy*)

Lab Test	Was the sample collected?	Collection time ( <i>00:00 - 23:59</i> )	Collection date and time (derived)
Nasopharyngeal Swab 1	No		
Nasopharyngeal Swab 2	No		

US3312637

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 15:20:08

Generated On: 09 Jun 2021 17:06:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312637

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 15:19:45

Generated On: 09 Jun 2021 17:06:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3312637

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 15:19:45

Generated On: 09 Jun 2021 17:06:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312637

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 15:19:45

Generated On: 09 Jun 2021 17:06:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3312637

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 15:19:45

Generated On: 09 Jun 2021 17:06:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312637

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 15:19:46

Generated On: 09 Jun 2021 17:06:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3312637

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 15:19:46

Generated On: 09 Jun 2021 17:06:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312637

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 15:20:10

Generated On: 09 Jun 2021 17:06:05

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

US3312637

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Apr 2021 15:20:10

Generated On: 09 Jun 2021 17:06:05

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	06 NOV 2020
Time of assessment (00:00-23:59)	10:17 (24 HR)
Vital Signs Date and Time (derived)	06 NOV 2020 10:17
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	83 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3312637

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 15:20:09

Generated On: 09 Jun 2021 17:06:05

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

06 NOV 2020

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

US3312637

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Apr 2021 15:20:09

Generated On: 09 Jun 2021 17:06:05

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

06 NOV 2020

Collection time (00:00-23:59)

10:29 (24 HR)

Collection date and time (derived)

06 NOV 2020 10:29

US3312637

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 15:20:09

Generated On: 09 Jun 2021 17:06:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3312637

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

<b>TIMEPOINT</b>	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 NOV 2020 12:14:02
Patient Cloud Open Date & Time	11 NOV 2020 00:01
Patient Cloud Close Date & Time	15 NOV 2020 23:59

US3312637

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

**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

18 NOV 2020 17:20:17

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

TIMEPOINT	DAY 75
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	22 NOV 2020 00:48:56
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

TIMEPOINT	DAY 82
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	29 NOV 2020 00:02:21
Patient Cloud Open Date & Time	29 NOV 2020 00:01
Patient Cloud Close Date & Time	03 DEC 2020 23:59

US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 DEC 2020 07:42:30
Patient Cloud Open Date & Time	06 DEC 2020 00:01
Patient Cloud Close Date & Time	10 DEC 2020 23:59

US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

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 type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 DEC 2020 08:35:06
Patient Cloud Open Date & Time	13 DEC 2020 00:01
Patient Cloud Close Date & Time	17 DEC 2020 23:59

US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

**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

20 DEC 2020 00:34:05

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

**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

27 DEC 2020 00:34:51

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59



US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

**TIMEPOINT**

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 JAN 2021 14:40:55

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 JAN 2021 00:02:43
Patient Cloud Open Date & Time	10 JAN 2021 00:01
Patient Cloud Close Date & Time	14 JAN 2021 23:59

US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

**TIMEPOINT**

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 JAN 2021 00:03:26

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

**TIMEPOINT**

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 JAN 2021 00:36:15

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

**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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 JAN 2021 00:02:28

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

**TIMEPOINT**

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 FEB 2021 00:21:27

Patient Cloud Open Date & Time

07 FEB 2021 00:01

Patient Cloud Close Date & Time

11 FEB 2021 23:59

US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 FEB 2021 12:00:13
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

**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

21 FEB 2021 21:26:56

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59



US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

**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

28 FEB 2021 00:26:51

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

**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

07 MAR 2021 01:00:07

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

**TIMEPOINT**

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 MAR 2021 05:25:02

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

**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

21 MAR 2021 00:54:54

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

**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

28 MAR 2021 13:30:53

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

**TIMEPOINT**

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 APR 2021 11:37:59

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

**TIMEPOINT**

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 APR 2021 00:02:58

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

**TIMEPOINT**

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 APR 2021 01:36:04

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59



US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

**TIMEPOINT**

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 APR 2021 13:36:09

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

**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

02 MAY 2021 01:56:15

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

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

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

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

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[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

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US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

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 <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"/>

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

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

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[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

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US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

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

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

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

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[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

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US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

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"/>

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

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

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[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

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US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

**TIMEPOINT**

DAY 271

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	06 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	10 JUN 2021 23:59

US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

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

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

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

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

US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

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

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

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



US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

**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 ☐

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

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

US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

**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 ☐

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

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

US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

**TIMEPOINT**

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

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

US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

**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 ☐

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

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

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[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

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US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

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"/>

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

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

US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

**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 ☐

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

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

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[Patient Cloud Open Date & Time](#)

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01 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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05 AUG 2021 23:59

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US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

**TIMEPOINT**

DAY 334

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

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

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[Patient Cloud Open Date & Time](#)

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08 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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12 AUG 2021 23:59

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US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

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"/>

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	15 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	19 AUG 2021 23:59
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US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

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"/>

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

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

US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

**TIMEPOINT**

DAY 355

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

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

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[Patient Cloud Open Date & Time](#)

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29 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 SEP 2021 23:59

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US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

**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 ☐

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

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

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[Patient Cloud Close Date & Time](#)

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09 SEP 2021 23:59

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US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

**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 ☐

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 SEP 2021 23:59



US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

**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 ☐

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

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

US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

**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 ☐

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

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

US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

**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 ☐

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

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

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[Patient Cloud Open Date & Time](#)

03 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

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US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

**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 ☐

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

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



US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

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

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	17 OCT 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	21 OCT 2021 23:59
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US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

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

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

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

US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

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

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

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

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[Patient Cloud Open Date & Time](#)

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31 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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04 NOV 2021 23:59

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US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

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"/>

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	07 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	11 NOV 2021 23:59



US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

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

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

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	14 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 NOV 2021 23:59

US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

**TIMEPOINT**

DAY 439

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

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

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[Patient Cloud Open Date & Time](#)

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21 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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25 NOV 2021 23:59

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US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

**TIMEPOINT**

DAY 446

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

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

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

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

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

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

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

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

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

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

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[Patient Cloud Open Date & Time](#)

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28 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 DEC 2021 23:59

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US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

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

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[Patient Cloud Open Date & Time](#)

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05 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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09 DEC 2021 23:59

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US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

**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 ☐  
Yes ☐

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

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

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

US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

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

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[Patient Cloud Close Date & Time](#)

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23 DEC 2021 23:59

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US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

**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 ☐

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

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

US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

**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 ☐

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

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

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[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

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US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

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="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"/>

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

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

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[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

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US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

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

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

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

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[Patient Cloud Open Date & Time](#)

16 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

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US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

**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 ☐

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

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

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[Patient Cloud Open Date & Time](#)

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23 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 JAN 2022 23:59

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US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

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

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

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

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

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[Patient Cloud Open Date & Time](#)

30 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

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US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

**TIMEPOINT**

DAY 516

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

**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 ☐

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

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

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[Patient Cloud Open Date & Time](#)

13 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

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US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

**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 ☐

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

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

US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

**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°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 ☐

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59



US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

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

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

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

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[Patient Cloud Open Date & Time](#)

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06 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 MAR 2022 23:59

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US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

**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 ☐

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

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

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[Patient Cloud Open Date & Time](#)

13 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

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US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

**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°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 ☐

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

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

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[Patient Cloud Open Date & Time](#)

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20 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 MAR 2022 23:59

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US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

**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 ☐

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

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

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[Patient Cloud Open Date & Time](#)

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27 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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31 MAR 2022 23:59

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US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

**TIMEPOINT**

DAY 572

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

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

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

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

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

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

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

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

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

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

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[Patient Cloud Open Date & Time](#)

03 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

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US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

**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 ☐

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

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

US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

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

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

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

**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 ☐

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

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

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[Patient Cloud Open Date & Time](#)

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24 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 APR 2022 23:59

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US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

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

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

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

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[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

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US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

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"/>

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

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

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[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

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US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

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

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 MAY 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 MAY 2022 23:59

US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

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"/>

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

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

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[Patient Cloud Open Date & Time](#)

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22 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 MAY 2022 23:59

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US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

**TIMEPOINT**

DAY 628

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

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

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

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

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

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

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

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

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

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

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

**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 ☐

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

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

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[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

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US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

**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 ☐

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

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

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[Patient Cloud Open Date & Time](#)

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12 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 JUN 2022 23:59

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US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

**TIMEPOINT**

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

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

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[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

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US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

**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 ☐

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

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

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[Patient Cloud Close Date & Time](#)

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30 JUN 2022 23:59

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US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

**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 ☐

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

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

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[Patient Cloud Open Date & Time](#)

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03 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 JUL 2022 23:59

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US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

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"/>

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

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

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[Patient Cloud Open Date & Time](#)

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10 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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14 JUL 2022 23:59

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US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

**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 ☐

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

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

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[Patient Cloud Open Date & Time](#)

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17 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 JUL 2022 23:59

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US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

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

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[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

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US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

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

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

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

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[Patient Cloud Open Date & Time](#)

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31 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 AUG 2022 23:59

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US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

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 <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"/>

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

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

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[Patient Cloud Open Date & Time](#)

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07 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 AUG 2022 23:59

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US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

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

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

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

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[Patient Cloud Open Date & Time](#)

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14 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 AUG 2022 23:59

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US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

**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 ☐

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 AUG 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 AUG 2022 23:59

US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

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="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"/>

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

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

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[Patient Cloud Open Date & Time](#)

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28 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 SEP 2022 23:59

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US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

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"/>

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

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

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[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

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US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

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 <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"/>

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

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

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[Patient Cloud Close Date & Time](#)

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15 SEP 2022 23:59

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US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

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"/>

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

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

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[Patient Cloud Open Date & Time](#)

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18 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 SEP 2022 23:59

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US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

**TIMEPOINT**

DAY 747

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

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

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

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

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

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

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

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

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

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

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[Patient Cloud Open Date & Time](#)

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25 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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29 SEP 2022 23:59

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US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

**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 ☐

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

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

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[Patient Cloud Open Date & Time](#)

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02 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 OCT 2022 23:59

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US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

**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 ☐

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

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

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[Patient Cloud Open Date & Time](#)

09 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

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US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

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"/>

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

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

US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

**TIMEPOINT**

DAY 775

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

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

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

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

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

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

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

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

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	23 OCT 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	27 OCT 2022 23:59
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US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

**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°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 ☐

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

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

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[Patient Cloud Open Date & Time](#)

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30 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 NOV 2022 23:59

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US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

**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 ☐

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

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

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[Patient Cloud Open Date & Time](#)

06 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

10 NOV 2022 23:59

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US3312637

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

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

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	13 NOV 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 NOV 2022 23:59

US3312637

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:06:05

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 17:50:50

US3312637

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 15:19:46

Generated On: 09 Jun 2021 17:06:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3312637

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 15:19:46

Generated On: 09 Jun 2021 17:06:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312637

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 15:19:45

Generated On: 09 Jun 2021 17:06:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

06 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3312637

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 15:19:45

Generated On: 09 Jun 2021 17:06:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312637

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 15:19:45

Generated On: 09 Jun 2021 17:06:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3312637

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 15:19:45

Generated On: 09 Jun 2021 17:06:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312637

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 15:19:45

Generated On: 09 Jun 2021 17:06:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3312637

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 15:19:45

Generated On: 09 Jun 2021 17:06:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312637

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 15:20:10

Generated On: 09 Jun 2021 17:06:05

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	31 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3312637

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Apr 2021 15:20:10

Generated On: 09 Jun 2021 17:06:05

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) \_\_\_\_\_

US3312637

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 15:20:10

Generated On: 09 Jun 2021 17:06:05

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.*

US3312637

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Apr 2021 15:20:10

Generated On: 09 Jun 2021 17:06:05

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

31 MAR 2021

Collection time (00:00-23:59)

09:48 (24 HR)

Collection date and time (derived)

31 MAR 2021 09:48

US3312637

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 15:20:10

Generated On: 09 Jun 2021 17:06:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



**US3312637**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:06:05**

Was Contact Attempted? Yes ☐  
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

**US3312637**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:06:05**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3312637

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:06:05

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

**US3312637**

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

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

**Generated On: 09 Jun 2021 17:06:05**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

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US3312637

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

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 15:19:44

Generated On: 09 Jun 2021 17:06:05

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

Visit date (dd MMM yyyy)	21 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3312637

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

Form: Unblinding

Data signed: (b) (4) 08 Apr 2021 15:19:44

Generated On: 09 Jun 2021 17:06:05

Date of updated informed consent ( <i>dd MMM yyyy</i> )	21 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding ( <i>dd MMM yyyy</i> )	21 JAN 2021
Participant randomization assignment	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/>
Actual Dose 1	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input type="radio"/> Not Administered <input checked="" type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	
Continuing with mRNA-1273	1

US3312637

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 08 Apr 2021 15:19:44

Generated On: 09 Jun 2021 17:06:05

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3312637

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 08 Apr 2021 15:19:44

Generated On: 09 Jun 2021 17:06:05

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)	21 JAN 2021
Time of assessment (00:00-23:59)	12:15 (24 HR)
Vital Signs Date and Time (derived)	21 JAN 2021 12:15
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)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG



US3312637

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 08 Apr 2021 15:19:44

Generated On: 09 Jun 2021 17:06:05

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)	21 JAN 2021
Time of assessment (00:00-23:59)	13:45 (24 HR)
Vital Signs Date and Time (derived)	21 JAN 2021 13:45
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3312637

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

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 15:19:44

Generated On: 09 Jun 2021 17:06:05

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 JAN 2021

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

US3312637

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

Form: Exposure

Data signed: (b) (4) 08 Apr 2021 15:19:44

Generated On: 09 Jun 2021 17:06:05

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) 21 JAN 2021

What was the treatment time? (00:00-23:59) 13:14 (24 HR)

Treatment Date and Time (derived) 21 JAN 2021 13:14

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

US3312637

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Apr 2021 15:19:44

Generated On: 09 Jun 2021 17:06:05

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

21 JAN 2021

Collection time (00:00-23:59)

11:54 (24 HR)

Collection date and time (derived)

21 JAN 2021 11:54

US3312637

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 08 Apr 2021 15:19:44

Generated On: 09 Jun 2021 17:06:05

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	21 JAN 2021
Collection time (00:00 - 23:59)	11:53
Collection Date and Time (derived)	21 JAN 2021 11:53

US3312637

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

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 15:19:44

Generated On: 09 Jun 2021 17:06:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312637

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 15:19:46

Generated On: 09 Jun 2021 17:06:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3312637

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 15:19:46

Generated On: 09 Jun 2021 17:06:05

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



US3312637

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 15:19:43

Generated On: 09 Jun 2021 17:06:05

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input checked="" type="radio"/>
	Clinic <input type="radio"/>
Folder OID	OLD29

US3312637

Folder: OL-D29 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Apr 2021 15:19:43

Generated On: 09 Jun 2021 17:06:05

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	18 FEB 2021
Time of assessment ( <i>00:00-23:59</i> )	11:16 (24 HR)
Vital Signs Date and Time (derived)	18 FEB 2021 11:16
Temperature ( <i>xxx.x</i> )	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	100 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3312637

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 15:19:43

Generated On: 09 Jun 2021 17:06:05

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 FEB 2021

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

US3312637

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Apr 2021 15:19:43

Generated On: 09 Jun 2021 17:06:05

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	18 FEB 2021
Collection time (00:00-23:59)	11:35 (24 HR)
Collection date and time (derived)	18 FEB 2021 11:35

US3312637

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Mar 2021 16:11:12

Generated On: 09 Jun 2021 17:06:05

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Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3312637

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Mar 2021 16:11:12

Generated On: 09 Jun 2021 17:06:05

AEID	USA-US300-2020-MRNA-1273-P30 1000006
Adverse event	EXACERBATION OF CORONARY ARTERY DISEASE
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 OCT 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)	16 OCT 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 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)	15 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	16 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
PRODUCTION RELEASE (v12.003 EAB) (1725)	317 of 1951

US3312637

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Mar 2021 16:11:12

Generated On: 09 Jun 2021 17:06:05

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 checked="" type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3312637

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Mar 2021 16:11:12

Generated On: 09 Jun 2021 17:06:05

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SUBJECT IS A 58 YEAR OLD  
GENTLEMAN WITH H/O  
SARCOIDOSIS, UMBILICAL  
HERNIA,  
HYPERCHOLESTEROLEMIA,  
HYPERTENSION, SVT AND  
ANGINA WHO WAS  
HOSPITALIZED AFTER  
CARDIAC CATHETERIZATION  
WITH STENT PLACEMENT,  
10/15/2020-10/16/2020.

SUBJECT WAS SEEN ON  
10/9/2020 FOR HIS D29 VISIT AT  
WHICH TIME HE DISCLOSED  
PLANS FOR UMBILICAL  
HERNIA REPAIR LEADING TO  
PRE-OPERATIVE TESTING,  
INCLUDING STRESS TEST  
WHICH WAS ABNORMAL AND  
WHICH LEAD TO PLANS FOR  
CARDIAC CATHETERIZATION  
(SCHEDULED FOR THE  
FOLLOWING WEEK). ON  
10/19/2020, SUBJECT REPORTED  
(VIA TELEPHONE) THAT  
CARDIAC CATHETERIZATION  
WITH STENT PLACEMENT  
TOOK PLACE ON 10/15/2020. HE  
WAS HOSPITALIZED  
POST-OPERATIVELY,  
OVERNIGHT, AND  
DISCHARGED ON 10/16/2020. HE  
DENIES ANY COMPLICATIONS  
AND REPORTED FEELING WELL  
AT LAST CONTACT. HE WAS



US3312637

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Mar 2021 16:11:12

Generated On: 09 Jun 2021 17:06:05

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DISCHARGED ON ASPIRIN  
325MG PO QD, ROSUVASTATIN  
40MG PO QD, FAMOTIDINE  
20MG PO QD, AND PRASUGREL  
10MG PO QD. PRIOR TO  
CARDIAC CATHETERIZATION  
HE HAD STARTED PRN  
SUBLINGUAL NITROGLYCERIN.  
HE PLANS TO CONTINUE  
FOLLOW-UP WITH HIS  
CARDIOLOGIST.  
IT IS NOTED THAT SUBJECT  
DID NOT DISCLOSE CARDIAC  
HISTORY OR UMBILICAL  
HERNIA AT SCREENING/D1  
VISIT. ON 10/9/2020, HE DID  
REPORT THAT UMBILICAL  
SURGICAL REPAIR WHICH HAS  
NOT TAKEN PLACE WAS  
PLANNED PRE-STUDY  
ENROLLMENT AND THAT  
HERNIA HAS NOT WORSENER.  
LIKEWISE, HE REPORTED  
ANGINA HAD BEEN PRESENT  
FOR TWO YEARS AND WHILE IT  
HAD PROGRESSIVELY  
WORSENER OVERALL SINCE  
ONSET, IT HAD NOT  
WORSENER AFTER STUDY  
ENROLLMENT.  
THIS IS AN SAE,  
HOSPITALIZATION, NOT  
RELATED TO IP. MEDICAL  
RECORDS WILL BE REQUESTED  
UPON RECEIPT OF SIGNED

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Mar 2021 16:11:12

Generated On: 09 Jun 2021 17:06:05

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MEDICAL RECORDS RELEASE  
FROM SUBJECT.MED RECS  
REVIEWED:HAD PRE-SURGICAL  
WORK-UP WITH CARDIAC  
STRESS ECHO THAT LEAD TO  
CARDIAC CATHETERIZATION  
WHICH SHOWED SIGNIFICANT  
CORONARY ARTERY DISEASE  
IN LEFT ANTERIOR  
DESCENDING (LAD) ARTERY  
AND MODERATE IN THE LEFT  
CIRCUMFLEX AND RIGHT  
CORONARY ARTERIES. THE  
LAD WAS STENTED 15OCT2020.  
SUBJECT HAS DONE WELL  
POST PROCEDURE AND HAS  
HAD NO PROBLEMS, CARDIAC  
EXAM GOOD AT LAST VISIT

---

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: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 08 Apr 2021 15:19:43

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

Yes ☒

No ☐

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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) 08 Apr 2021 15:19:40

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Name of Medication FLUOXETIN

Prophylaxis Yes ☐  
No ☒

Indication DEPRESSION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 15:19:40

Generated On: 09 Jun 2021 17:06:05

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2001	
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) 08 Apr 2021 15:19:40

Generated On: 09 Jun 2021 17:06:05

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐  
No ☒

Indication GASTROESOPHAGEAL REFLUX  
DISEASE

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 15:19:40

Generated On: 09 Jun 2021 17:06:05

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2001
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 15:19:40

Generated On: 09 Jun 2021 17:06:05

Name of Medication CPAP

Prophylaxis Yes ☐  
No ☒

Indication SLEEP APNEA

Dose per administration 1

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

If dose unit is Other, specify UNIT

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 NIGHTLY AT BEDTIME

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) 08 Apr 2021 15:19:40

Generated On: 09 Jun 2021 17:06:05

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input checked="" type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 15:19:40

Generated On: 09 Jun 2021 17:06:05

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐  
No ☒

Indication MUSCLE ACHES

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) 08 Apr 2021 15:19:40

Generated On: 09 Jun 2021 17:06:05

	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 SEP 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 SEP 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Apr 2021 15:19:40

Generated On: 09 Jun 2021 17:06:05

Name of Medication NITROGLYCERIN

Prophylaxis Yes ☐  
No ☒

Indication ANGINA

Dose per administration 0.3

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) 08 Apr 2021 15:19:40

Generated On: 09 Jun 2021 17:06:05

	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 checked="" type="checkbox"/>
If route of administration is Other, specify	SUBLINGUAL	
Start date (dd MMM yyyy)	09 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 15:19:40

Generated On: 09 Jun 2021 17:06:05

Name of Medication ASPIRIN

Prophylaxis Yes ☒  
No ☐

Indication CARDIAC PROPHYLAXIS

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 (6)

Data signed: (b) (4) 08 Apr 2021 15:19:40

Generated On: 09 Jun 2021 17:06:05

	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 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Apr 2021 15:19:40

Generated On: 09 Jun 2021 17:06:05

Name of Medication ROSUVASTATIN

Prophylaxis Yes ☐  
No ☒

Indication HYPERCHOLESTEROLEMIA

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 (7)

Data signed: (b) (4) 08 Apr 2021 15:19:40

Generated On: 09 Jun 2021 17:06:05

	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 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 08 Apr 2021 15:19:40

Generated On: 09 Jun 2021 17:06:05

Name of Medication FAMOTIDINE

Prophylaxis Yes ☐  
No ☒

Indication GASTROESOPHAGEAL REFLUX  
DISEASE

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 08 Apr 2021 15:19:40

Generated On: 09 Jun 2021 17:06:05

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	16 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 08 Apr 2021 15:19:40

Generated On: 09 Jun 2021 17:06:05

Name of Medication PRASUGREL

Prophylaxis Yes ☐  
No ☒

Indication CORONARY ARTERY DISEASE

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 (9)

Data signed: (b) (4) 08 Apr 2021 15:19:40

Generated On: 09 Jun 2021 17:06:05

	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 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 08 Apr 2021 15:19:40

Generated On: 09 Jun 2021 17:06:05

Name of Medication PRASUGREL

Prophylaxis Yes ☐  
No ☒

Indication CORANARY ARTERY DISEASE

Dose per administration 60

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 08 Apr 2021 15:19:40

Generated On: 09 Jun 2021 17:06:05

	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 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		15 OCT 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"/>

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 08 Apr 2021 15:19:40

Generated On: 09 Jun 2021 17:06:05

Name of Medication TRAZADONE

Prophylaxis Yes ☐  
No ☒

Indication DIFFICULTY SLEEPING

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 08 Apr 2021 15:19:40

Generated On: 09 Jun 2021 17:06:05

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

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 08 Apr 2021 15:19:40

Generated On: 09 Jun 2021 17:06:05

Name of Medication SEROQUEL

Prophylaxis Yes ☐  
No ☒

Indication DEPRESSION

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 08 Apr 2021 15:19:40

Generated On: 09 Jun 2021 17:06:05

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2001	
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"/>

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 08 Apr 2021 15:19:40

Generated On: 09 Jun 2021 17:06:05

Name of Medication HYDROCODONE 7.5MG/  
ACETAMINOPHEN 325 MG

Prophylaxis Yes ☐  
No ☒

Indication UMBILICAL HERNIA

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 08 Apr 2021 15:19:40

Generated On: 09 Jun 2021 17:06:05

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		30 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)		06 JAN 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"/>

US3312637

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 08 Apr 2021 15:19:43

Generated On: 09 Jun 2021 17:06:05

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3312637

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 25 Apr 2021 14:21:53

Generated On: 09 Jun 2021 17:06:05

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
15 OCT 2020	CARDIAC CATHETERIZATION WITH STENT	Adverse Event	
30 DEC 2020	UMBILICAL HERNIA REPAIR	Medical History	

US3312637

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 08 Apr 2021 15:19:43

Generated On: 09 Jun 2021 17:06:05

Date of dosing discontinuation (dd MMM yyyy) 20 OCT 2020

Primary reason for dosing discontinuation

AE (specify)	<input checked="" type="radio"/>
SAE (specify)	<input type="radio"/>
Death	<input type="radio"/>
Lost To Follow-up	<input type="radio"/>
Physician decision (specify)	<input type="radio"/>
Pregnancy	<input type="radio"/>
Protocol deviation (specify)	<input type="radio"/>
Study Terminated By Sponsor	<input type="radio"/>
Withdrawal of consent by participant (specify)	<input type="radio"/>
Due to SARS-COV-2	<input type="radio"/>
Other	<input type="radio"/>

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

AE #1



US3312637

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:06:05

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 ☐

US3312637

Folder: SAE USA-US300-2020-MRNA-1273-P301000006

Form: Safety Report Form

Data signed: (b) (4) 08 Apr 2021 15:19:44

Generated On: 09 Jun 2021 17:06:05

SAEID	USA-US300-2020-MRNA-1273-P301000006
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)	3

US3312637

Folder: SAE USA-US300-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Data signed: (b) (4) 08 Apr 2021 15:19:44

Generated On: 09 Jun 2021 17:06:05

SAEID	USA-US300-2020-MRNA-1273-P301000006
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)	3
Date of submission (Pre-filled from custom function)	21/OCT/2020 18:12
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

US3312637

Folder: SAE USA-US300-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Data signed: (b) (4) 08 Apr 2021 15:19:44

Generated On: 09 Jun 2021 17:06:05

SAEID	USA-US300-2020-MRNA-1273-P301000006
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)	3
Date of submission (Pre-filled from custom function)	05/NOV/2020 18:25
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

US3312637

Folder: SAE USA-US300-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Data signed: (b) (4) 08 Apr 2021 15:19:44

Generated On: 09 Jun 2021 17:06:05

SAEID	USA-US300-2020-MRNA-1273-P301000006
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)	3
Date of submission (Pre-filled from custom function)	11/NOV/2020 21:52
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

US3312637 (Prod: Johnson County Clin-Trials)

**US3312637**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 17:06:05**

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:57:34
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'US3312637'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 18:47:51

US3312637

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:06:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 20:30:14
User entered 'Yes (Y)'	Christa Estrada (b) (4)	11 Sep 2020 20:38:03



US3312637

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:06:05

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 20:30:14
User entered '11 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 18:47:52

US3312637

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:06:05

[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 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 20:30:14
User entered 'Clinic (Clinic)'	Christa Estrada (b) (4)	11 Sep 2020 20:38:03

**US3312637**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:06:05**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered 'SCRN'	System	11 Sep 2020 20:38:03

US3312637

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:05

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 20:30:38
User entered (b) (6) 1962'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 18:47:53

US3312637

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:05

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 20:30:38
User entered '57'	Christa Estrada (b) (4)	11 Sep 2020 20:38:27

**US3312637**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:06:05**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered 'YEARS'	System	11 Sep 2020 20:38:27

US3312637

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:05

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered '57'	System	11 Sep 2020 20:38:43

US3312637

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:05

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 20:30:38
User entered 'Male (M)'	Christa Estrada (b) (4)	11 Sep 2020 20:38:27



US3312637

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:05

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 20:30:38
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Christa Estrada (b) (4)	11 Sep 2020 20:38:27

**US3312637**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:06:05**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 20:30:38
User entered '0'	Christa Estrada (b) (4)	11 Sep 2020 20:38:27

US3312637

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:05

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 20:30:38
User entered 'l'	Christa Estrada (b) (4)	11 Sep 2020 20:38:27

US3312637

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:05

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 20:30:38
User entered '0'	Christa Estrada (b) (4)	11 Sep 2020 20:38:27

**US3312637**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:06:05**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 20:30:38
User entered '0'	Christa Estrada (b) (4)	11 Sep 2020 20:38:27

**US3312637**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:06:05**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 20:30:38
User entered '0'	Christa Estrada (b) (4)	11 Sep 2020 20:38:27

US3312637

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:05

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 20:30:38
User entered '0'	Christa Estrada (b) (4)	11 Sep 2020 20:38:27

US3312637

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:05

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 20:30:38
User entered empty.	Christa Estrada (b) (4)	11 Sep 2020 20:38:27



**US3312637**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:06:05**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 20:30:38
User entered '0'	Christa Estrada (b) (4)	11 Sep 2020 20:38:27

US3312637

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:05

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 20:30:38
User entered '0'	Christa Estrada (b) (4)	11 Sep 2020 20:38:27

US3312637

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:06:05

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 20:33:45
User entered '11 Sep 2020'	Christa Estrada (b) (4)	11 Sep 2020 20:38:43

**US3312637**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:06:05**

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered 'Sep 2020'	System	11 Sep 2020 20:38:43

**US3312637**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:06:05**

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered '2020'	System	11 Sep 2020 20:38:43

US3312637

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:06:05

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 20:33:45
User entered 'Amendment 3 (3)'	Christa Estrada (b) (4)	11 Sep 2020 20:38:43

US3312637

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:06:05

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 20:33:45
User entered 'Yes (Y)'	Christa Estrada (b) (4)	11 Sep 2020 20:38:43

**US3312637**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:06:05**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 20:33:45
User entered empty.	Christa Estrada (b) (4)	11 Sep 2020 20:38:43



US3312637

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:06:05

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 20:33:45
User entered empty.	Christa Estrada (b) (4)	11 Sep 2020 20:38:43

US3312637

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:06:05

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 20:33:45
User entered 'No (N)'	Christa Estrada (b) (4)	11 Sep 2020 20:38:43

US3312637

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:06:05

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 20:33:45
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 18:47:52

US3312637

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:06:05

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered 'I'	System	11 Sep 2020 20:38:50

US3312637

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:06:05

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 20:33:54
User entered 'Yes (Y)'	Christa Estrada (b) (4)	11 Sep 2020 20:38:50

US3312637

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:06:05

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 20:35:01
User entered 'Yes (Y)'	Karol Moore (b) (4)	30 Sep 2020 23:13:52

US3312637

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:06:05

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User coded data point as SOC: Immune system disorders, HLGT: Immune disorders NEC, HLT: Acute and chronic sarcoidosis, PT: Sarcoidosis, LLT: Sarcoidosis - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 23:15:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 23:15:39
Data point term sent to Coder	System	30 Sep 2020 23:14:39
User entered 'sarcoidosis'	Karol Moore (b) (4)	30 Sep 2020 23:14:16

**US3312637**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:06:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'un UNK 1986'	Karol Moore (b) (4)	30 Sep 2020 23:14:16



**US3312637**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:06:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '0'	Karol Moore (b) (4)	30 Sep 2020 23:14:16

**US3312637**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:06:05**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Yes (Y)'	Karol Moore (b) (4)	30 Sep 2020 23:14:16

**US3312637**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:06:05**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered empty.	Karol Moore (b) (4)	30 Sep 2020 23:14:16

**US3312637**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:06:05**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '0'	Karol Moore (b) (4)	30 Sep 2020 23:14:16

**US3312637**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:06:05**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered 'Jan 1986'	System	30 Sep 2020 23:14:16

**US3312637**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:06:05**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered '1986'	System	30 Sep 2020 23:14:16

US3312637

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:06:05

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered empty.	System	30 Sep 2020 23:14:16

**US3312637**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:06:05**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered empty.	System	30 Sep 2020 23:14:16



US3312637

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:06:05

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 23:15:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 23:15:38
Data point term sent to Coder	System	30 Sep 2020 23:14:39
User entered 'Gastroesophageal reflux disease'	Karol Moore (b) (4)	30 Sep 2020 23:14:27

**US3312637**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:06:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'un UNK 2001'	Karol Moore (b) (4)	30 Sep 2020 23:14:27

**US3312637**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:06:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '0'	Karol Moore (b) (4)	30 Sep 2020 23:14:27

**US3312637**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:06:05**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Yes (Y)'	Karol Moore (b) (4)	30 Sep 2020 23:14:27

**US3312637**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:06:05**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered empty.	Karol Moore (b) (4)	30 Sep 2020 23:14:27

**US3312637**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:06:05**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '0'	Karol Moore (b) (4)	30 Sep 2020 23:14:27

**US3312637**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:06:05**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered 'Jan 2001'	System	30 Sep 2020 23:14:27

**US3312637**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:06:05**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered '2001'	System	30 Sep 2020 23:14:27



US3312637

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:06:05

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered empty.	System	30 Sep 2020 23:14:27

**US3312637**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:06:05**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered empty.	System	30 Sep 2020 23:14:27

US3312637

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:06:05

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 23:15:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 23:15:38
Data point term sent to Coder	System	30 Sep 2020 23:14:39
User entered 'depression'	Karol Moore (b) (4)	30 Sep 2020 23:14:38

**US3312637**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:06:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'un UNK 2001'	Karol Moore (b) (4)	30 Sep 2020 23:14:38

**US3312637**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:06:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '0'	Karol Moore (b) (4)	30 Sep 2020 23:14:38

**US3312637**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:06:05**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Yes (Y)'	Karol Moore (b) (4)	30 Sep 2020 23:14:38

**US3312637**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:06:05**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered empty.	Karol Moore (b) (4)	30 Sep 2020 23:14:38

**US3312637**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:06:05**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '0'	Karol Moore (b) (4)	30 Sep 2020 23:14:38



**US3312637**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:06:05**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered 'Jan 2001'	System	30 Sep 2020 23:14:38

**US3312637**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:06:05**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered '2001'	System	30 Sep 2020 23:14:38

**US3312637**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:06:05**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered empty.	System	30 Sep 2020 23:14:38

**US3312637**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:06:05**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered empty.	System	30 Sep 2020 23:14:38

US3312637

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:06:05

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc protrusion, LLT: Intervertebral disc bulging - version MedDRA\\23.0.	Coder Import (b) (4)	17 Nov 2020 08:20:54
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	17 Nov 2020 08:20:54
Data point term sent to Coder	System	10 Nov 2020 20:11:17
Coding entries removed.	(b) (4), (b) (6)	10 Nov 2020 20:11:02
User entered 'L4-L5 bulging disc' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 20:11:02
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Spinal fractures and dislocations, PT: Lumbar vertebral fracture, LLT: Lumbar vertebral fracture - version MedDRA\\23.0.	Coder Import (b) (4)	01 Oct 2020 06:15:10
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	01 Oct 2020 06:15:10
Data point term sent to Coder	System	30 Sep 2020 23:15:41
User entered 'l4-15 fracture'	Karol Moore (b) (4)	30 Sep 2020 23:15:04

**US3312637**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:06:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '06 Sep 2017'	Karol Moore (b) (4)	30 Sep 2020 23:15:04

**US3312637**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:06:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '0'	Karol Moore (b) (4)	30 Sep 2020 23:15:04

**US3312637**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:06:05**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'No (N)'	Karol Moore (b) (4)	30 Sep 2020 23:15:04



**US3312637**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:06:05**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '06 Sep 2017'	Karol Moore (b) (4)	30 Sep 2020 23:15:04

**US3312637**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:06:05**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '0'	Karol Moore (b) (4)	30 Sep 2020 23:15:04

**US3312637**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:06:05**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered 'Sep 2017'	System	30 Sep 2020 23:15:04

US3312637

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:06:05

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered '2017'	System	30 Sep 2020 23:15:04

**US3312637**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:06:05**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered 'Sep 2017'	System	30 Sep 2020 23:15:04

US3312637

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:06:05

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered '2017'	System	30 Sep 2020 23:15:04

US3312637

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:06:05

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Humerus fracture, LLT: Compound fracture - humerus - version MedDRA\23.0.	Coder Import (b) (4)	01 Oct 2020 06:11:13
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	01 Oct 2020 06:11:13
Data point term sent to Coder	System	30 Sep 2020 23:16:44
User entered 'left humerus compound fracture'	Karol Moore (b) (4)	30 Sep 2020 23:16:04

**US3312637**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:06:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '06 Sep 2017'	Karol Moore (b) (4)	30 Sep 2020 23:16:04



**US3312637**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:06:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '0'	Karol Moore (b) (4)	30 Sep 2020 23:16:04

**US3312637**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:06:05**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'No (N)'	Karol Moore (b) (4)	30 Sep 2020 23:16:04

**US3312637**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:06:05**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '06 Sep 2017'	Karol Moore (b) (4)	30 Sep 2020 23:16:04

**US3312637**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:06:05**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '0'	Karol Moore (b) (4)	30 Sep 2020 23:16:04

US3312637

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:06:05

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered 'Sep 2017'	System	30 Sep 2020 23:16:04

US3312637

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:06:05

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered '2017'	System	30 Sep 2020 23:16:04

**US3312637**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:06:05**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered 'Sep 2017'	System	30 Sep 2020 23:16:04

US3312637

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:06:05

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered '2017'	System	30 Sep 2020 23:16:04



US3312637

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:06:05

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Fracture treatments (excl skull and spine), PT: Fracture treatment, LLT: Fracture repair - version MedDRA\\23.0.	Coder Import (b) (4)	01 Oct 2020 06:11:13
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	01 Oct 2020 06:11:13
Data point term sent to Coder	System	30 Sep 2020 23:16:42
User entered 'left humerous compound fracture surgical repair'	Karol Moore (b) (4)	30 Sep 2020 23:16:40

**US3312637**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:06:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '06 Sep 2017'	Karol Moore (b) (4)	30 Sep 2020 23:16:40

US3312637

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:06:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '0'	Karol Moore (b) (4)	30 Sep 2020 23:16:40

**US3312637**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:06:05**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'No (N)'	Karol Moore (b) (4)	30 Sep 2020 23:16:40

**US3312637**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:06:05**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '06 Sep 2017'	Karol Moore (b) (4)	30 Sep 2020 23:16:40

**US3312637**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:06:05**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '0'	Karol Moore (b) (4)	30 Sep 2020 23:16:40

**US3312637**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:06:05**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered 'Sep 2017'	System	30 Sep 2020 23:16:40

**US3312637**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:06:05**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered '2017'	System	30 Sep 2020 23:16:40



**US3312637**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:06:05**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered 'Sep 2017'	System	30 Sep 2020 23:16:40

**US3312637**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:06:05**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered '2017'	System	30 Sep 2020 23:16:40

US3312637

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:06:05

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User coded data point as SOC: Surgical and medical procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 23:18:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 23:18:39
Data point term sent to Coder	System	30 Sep 2020 23:17:45
User entered 'cholecystectomy'	Karol Moore (b) (4)	30 Sep 2020 23:16:56

**US3312637**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:06:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'un UNK 2001'	Karol Moore (b) (4)	30 Sep 2020 23:16:56

**US3312637**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:06:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '0'	Karol Moore (b) (4)	30 Sep 2020 23:16:56

**US3312637**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:06:05**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'No (N)'	Karol Moore (b) (4)	30 Sep 2020 23:16:56

**US3312637**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:06:05**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'un UNK 2001'	Karol Moore (b) (4)	30 Sep 2020 23:16:56

**US3312637**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:06:05**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '0'	Karol Moore (b) (4)	30 Sep 2020 23:16:56



**US3312637**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:06:05**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered 'Jan 2001'	System	30 Sep 2020 23:16:56

**US3312637**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:06:05**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered '2001'	System	30 Sep 2020 23:16:56

**US3312637**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:06:05**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered 'Jan 2001'	System	30 Sep 2020 23:16:56

**US3312637**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:06:05**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered '2001'	System	30 Sep 2020 23:16:56

US3312637

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:06:05

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholelithiasis, LLT: Cholelithiasis - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 23:18:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 23:18:39
Data point term sent to Coder	System	30 Sep 2020 23:17:45
User entered 'cholelithiasis'	Karol Moore (b) (4)	30 Sep 2020 23:17:10

**US3312637**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:06:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'un UNK 2001'	Karol Moore (b) (4)	30 Sep 2020 23:17:10

**US3312637**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:06:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '0'	Karol Moore (b) (4)	30 Sep 2020 23:17:10

**US3312637**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:06:05**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'No (N)'	Karol Moore (b) (4)	30 Sep 2020 23:17:10



**US3312637**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:06:05**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'un UNK 2001'	Karol Moore (b) (4)	30 Sep 2020 23:17:10

**US3312637**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:06:05**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '0'	Karol Moore (b) (4)	30 Sep 2020 23:17:10

**US3312637**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:06:05**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered 'Jan 2001'	System	30 Sep 2020 23:17:10

US3312637

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:06:05

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered '2001'	System	30 Sep 2020 23:17:10

US3312637

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:06:05

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered 'Jan 2001'	System	30 Sep 2020 23:17:10

**US3312637**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:06:05**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered '2001'	System	30 Sep 2020 23:17:10

US3312637

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:06:05

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Sleep apnea - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 23:18:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 23:18:39
Data point term sent to Coder	System	30 Sep 2020 23:17:46
User entered 'sleep apnea'	Karol Moore (b) (4)	30 Sep 2020 23:17:22

**US3312637**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:06:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'un UNK 2015'	Karol Moore (b) (4)	30 Sep 2020 23:17:22



**US3312637**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:06:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '0'	Karol Moore (b) (4)	30 Sep 2020 23:17:22

**US3312637**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:06:05**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Yes (Y)'	Karol Moore (b) (4)	30 Sep 2020 23:17:22

**US3312637**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:06:05**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered empty.	Karol Moore (b) (4)	30 Sep 2020 23:17:22

**US3312637**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:06:05**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '0'	Karol Moore (b) (4)	30 Sep 2020 23:17:22

**US3312637**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:06:05**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered 'Jan 2015'	System	30 Sep 2020 23:17:22

**US3312637**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:06:05**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered '2015'	System	30 Sep 2020 23:17:22

**US3312637**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:06:05**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered empty.	System	30 Sep 2020 23:17:22

**US3312637**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:06:05**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered empty.	System	30 Sep 2020 23:17:22



US3312637

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:06:05

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Umbilical hernias, PT: Umbilical hernia, LLT: Umbilical hernia - version MedDRA\\23.0.	Coder Import (b) (4)	04 Nov 2020 09:35:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Nov 2020 09:35:01
Data point term sent to Coder	System	02 Nov 2020 15:13:14
User entered 'umbilical hernia'	Karol Moore (b) (4)	02 Nov 2020 15:12:43

**US3312637**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:06:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'un UNK 2000'	Karol Moore (b) (4)	02 Nov 2020 15:12:43

**US3312637**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:06:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '0'	Karol Moore (b) (4)	02 Nov 2020 15:12:43

**US3312637**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:06:05**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Yes (Y)'	Karol Moore (b) (4)	02 Nov 2020 15:12:43

**US3312637**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:06:05**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered empty.	Karol Moore (b) (4)	02 Nov 2020 15:12:43

**US3312637**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:06:05**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '0'	Karol Moore (b) (4)	02 Nov 2020 15:12:43

US3312637

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:06:05

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered 'Jan 2000'	System	02 Nov 2020 15:12:43

**US3312637**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:06:05**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered '2000'	System	02 Nov 2020 15:12:43



US3312637

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:06:05

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered empty.	System	02 Nov 2020 15:12:43

**US3312637**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:06:05**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered empty.	System	02 Nov 2020 15:12:43

US3312637

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:06:05

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4)	04 Nov 2020 09:34:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Nov 2020 09:34:58
Data point term sent to Coder	System	02 Nov 2020 15:13:16
User entered 'hypercholesterolemia'	Karol Moore (b) (4)	02 Nov 2020 15:13:06

**US3312637**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:06:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'un UNK 1990'	Karol Moore (b) (4)	02 Nov 2020 15:13:06

**US3312637**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:06:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '0'	Karol Moore (b) (4)	02 Nov 2020 15:13:06

**US3312637**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:06:05**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Yes (Y)'	Karol Moore (b) (4)	02 Nov 2020 15:13:06

**US3312637**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:06:05**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered empty.	Karol Moore (b) (4)	02 Nov 2020 15:13:06

**US3312637**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:06:05**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '0'	Karol Moore (b) (4)	02 Nov 2020 15:13:06



US3312637

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:06:05

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered 'Jan 1990'	System	02 Nov 2020 15:13:06

**US3312637**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:06:05**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered '1990'	System	02 Nov 2020 15:13:06

US3312637

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:06:05

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered empty.	System	02 Nov 2020 15:13:06

**US3312637**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:06:05**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered empty.	System	02 Nov 2020 15:13:06

US3312637

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:06:05

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 13:34:07
Query 'Per DM CLR: Please note that there is no Con Karol Moore Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'Per SOURCE, HYPERTENSION IS UNTREATED' (Site from DM).	(b) (4)	15 Mar 2021 20:28:00
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	10 Jan 2021 07:13:50
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) (b) (4)	04 Nov 2020 09:35:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Nov 2020 09:35:06
Data point term sent to Coder	System	02 Nov 2020 15:14:17
User entered 'hypertension'	Karol Moore (b) (4)	02 Nov 2020 15:13:51

**US3312637**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 17:06:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'un UNK 2017'	Karol Moore (b) (4)	02 Nov 2020 15:13:51

**US3312637**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 17:06:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '0'	Karol Moore (b) (4)	02 Nov 2020 15:13:51

**US3312637**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 17:06:05**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Yes (Y)'	Karol Moore (b) (4)	02 Nov 2020 15:13:51



**US3312637**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 17:06:05**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered empty.	Karol Moore (b) (4)	02 Nov 2020 15:13:51

**US3312637**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 17:06:05**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '0'	Karol Moore (b) (4)	02 Nov 2020 15:13:51

**US3312637**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 17:06:05**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered 'Jan 2017'	System	02 Nov 2020 15:13:51

US3312637

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:06:05

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered '2017'	System	02 Nov 2020 15:13:51

**US3312637**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 17:06:05**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered empty.	System	02 Nov 2020 15:13:51

**US3312637**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 17:06:05**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered empty.	System	02 Nov 2020 15:13:51

US3312637

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:06:05

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Supraventricular tachycardia, LLT: Supraventricular tachycardia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Nov 2020 09:58:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Nov 2020 09:58:46
Data point term sent to Coder	System	02 Nov 2020 15:15:18
User entered 'Supraventricular tachycardia'	Karol Moore (b) (4) (b) (4)	02 Nov 2020 15:14:59

**US3312637**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 17:06:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'un UNK 1980'	Karol Moore (b) (4)	02 Nov 2020 15:14:59



**US3312637**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 17:06:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '0'	Karol Moore (b) (4)	02 Nov 2020 15:14:59

**US3312637**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 17:06:05**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Yes (Y)'	Karol Moore (b) (4)	02 Nov 2020 15:14:59

**US3312637**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 17:06:05**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered empty.	Karol Moore (b) (4)	02 Nov 2020 15:14:59

**US3312637**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 17:06:05**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '0'	Karol Moore (b) (4)	02 Nov 2020 15:14:59

US3312637

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:06:05

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered 'Jan 1980'	System	02 Nov 2020 15:14:59

US3312637

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:06:05

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered '1980'	System	02 Nov 2020 15:14:59

**US3312637**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 17:06:05**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered empty.	System	02 Nov 2020 15:14:59

**US3312637**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 17:06:05**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered empty.	System	02 Nov 2020 15:14:59



US3312637

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:06:05

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
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)	04 Nov 2020 10:52:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Nov 2020 10:52:26
Data point term sent to Coder	System	02 Nov 2020 15:22:24
User entered 'angina'	Karol Moore (b) (4)	02 Nov 2020 15:21:52

**US3312637**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 17:06:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'un UNK 2018'	Karol Moore (b) (4)	02 Nov 2020 15:21:52

**US3312637**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 17:06:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '0'	Karol Moore (b) (4)	02 Nov 2020 15:21:52

**US3312637**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 17:06:05**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Yes (Y)'	Karol Moore (b) (4)	02 Nov 2020 15:21:52

**US3312637**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 17:06:05**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered empty.	Karol Moore (b) (4)	02 Nov 2020 15:21:52

**US3312637**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 17:06:05**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '0'	Karol Moore (b) (4)	02 Nov 2020 15:21:52

US3312637

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:06:05

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered 'Jan 2018'	System	02 Nov 2020 15:21:52

**US3312637**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 17:06:05**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered '2018'	System	02 Nov 2020 15:21:52



**US3312637**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 17:06:05**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered empty.	System	02 Nov 2020 15:21:52

**US3312637**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 17:06:05**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered empty.	System	02 Nov 2020 15:21:52

US3312637

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:06:05

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User coded data point as SOC: Nervous system disorders, HLGT: Spinal cord and nerve root disorders, HLT: Lumbar spinal cord and nerve root disorders, PT: Sciatica, LLT: Sciatica - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 19:49:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 19:49:39
Data point term sent to Coder	System	10 Nov 2020 19:48:38
User entered 'sciatica'	(b) (4), (b) (6)	10 Nov 2020 19:48:22

**US3312637**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 17:06:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'un UNK 2017'	(b) (4), (b) (6)	10 Nov 2020 19:48:22

**US3312637**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 17:06:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '0'	(b) (4), (b) (6)	10 Nov 2020 19:48:22

**US3312637**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 17:06:05**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 19:48:22

**US3312637**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 17:06:05**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 19:48:22

**US3312637**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 17:06:05**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '0'	(b) (4), (b) (6)	10 Nov 2020 19:48:22



US3312637

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:06:05

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered 'Jan 2017'	System	10 Nov 2020 19:48:22

**US3312637**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 17:06:05**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered '2017'	System	10 Nov 2020 19:48:22

US3312637

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:06:05

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered empty.	System	10 Nov 2020 19:48:22

**US3312637**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 17:06:05**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered empty.	System	10 Nov 2020 19:48:22

US3312637

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:06:05

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Low back pain - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 19:50:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 19:50:40
Data point term sent to Coder	System	10 Nov 2020 19:49:39
User entered 'low back pain'	(b) (4), (b) (6)	10 Nov 2020 19:48:43

US3312637

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:06:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Nov 2020 19:49:02
User entered 'Un UNK 2017' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 19:49:02
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Nov 2020 19:48:43
User entered 'u UNK 2017' (non-conformant).	(b) (4), (b) (6)	10 Nov 2020 19:48:43

**US3312637**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 17:06:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '0'	(b) (4), (b) (6)	10 Nov 2020 19:48:43

**US3312637**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 17:06:05**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 19:48:43



**US3312637**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 17:06:05**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 19:48:43

**US3312637**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 17:06:05**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '0'	(b) (4), (b) (6)	10 Nov 2020 19:48:43

US3312637

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:06:05

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered 'Jan 2017'	System	10 Nov 2020 19:49:02
User entered empty.	System	10 Nov 2020 19:48:43

**US3312637**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 17:06:05**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered '2017'	System	10 Nov 2020 19:49:02
User entered empty.	System	10 Nov 2020 19:48:43

US3312637

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:06:05

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered empty.	System	10 Nov 2020 19:48:43

**US3312637**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 17:06:05**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered empty.	System	10 Nov 2020 19:48:43

US3312637

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:06:05

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User coded data point as SOC: Psychiatric disorders, HLTG: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Difficulty sleeping - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 20:13:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 20:13:50
Data point term sent to Coder	System	10 Nov 2020 20:13:19
User entered 'difficulty sleeping'	(b) (4), (b) (6)	10 Nov 2020 20:12:59

US3312637

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:06:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'UN UNK 2017' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 20:16:47
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Nov 2020 20:14:21
User entered 'un UNK 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 20:14:21
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Nov 2020 20:13:54
User entered ' UNK 2020' (non-conformant).	(b) (4), (b) (6)	10 Nov 2020 20:13:54
User entered '06 Sep 2020'	(b) (4), (b) (6)	10 Nov 2020 20:12:59



**US3312637**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 17:06:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '0'	(b) (4), (b) (6)	10 Nov 2020 20:12:59

**US3312637**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 17:06:05**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 20:12:59

**US3312637**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 17:06:05**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 20:12:59

**US3312637**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 17:06:05**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '0'	(b) (4), (b) (6)	10 Nov 2020 20:12:59

**US3312637**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 17:06:05**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered 'Jan 2017'	System	10 Nov 2020 20:16:47
User entered 'Jan 2020'	System	10 Nov 2020 20:14:21
User entered empty.	System	10 Nov 2020 20:13:54
User entered 'Sep 2020'	System	10 Nov 2020 20:12:59

**US3312637**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 17:06:05**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered '2017'	System	10 Nov 2020 20:16:47
User entered '2020'	System	10 Nov 2020 20:14:21
User entered empty.	System	10 Nov 2020 20:13:54
User entered '2020'	System	10 Nov 2020 20:12:59

US3312637

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:06:05

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered empty.	System	10 Nov 2020 20:12:59

**US3312637**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 17:06:05**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered empty.	System	10 Nov 2020 20:12:59



US3312637

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:06:05

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	13 Nov 2020 15:00:12
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.	Coder Import (b) (4) (b) (4)	10 Nov 2020 20:34:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 20:34:41
Data point term sent to Coder	System	10 Nov 2020 20:34:08
User entered 'coronary artery disease' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 20:33:26
Data point term sent to Coder	System	10 Nov 2020 20:15:24
Query 'Data is required. Please complete.' answered with 'NA' (Site from System).	(b) (4), (b) (6)	10 Nov 2020 20:15:03
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 20:14:47
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 20:14:47
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Low back pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 20:13:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 20:13:50
Data point term sent to Coder	System	10 Nov 2020 20:13:19
User entered 'low back pain'	(b) (4), (b) (6)	10 Nov 2020 20:13:14

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Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:06:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User closed query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	10 Nov 2020 20:33:26
User entered 'un UNK 2018' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 20:33:26
User opened query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	10 Nov 2020 20:14:47
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 20:14:47
User entered '06 Sep 2020'	(b) (4), (b) (6)	10 Nov 2020 20:13:14

**US3312637**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 17:06:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '0'	(b) (4), (b) (6)	10 Nov 2020 20:13:14

US3312637

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:06:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	13 Nov 2020 15:00:16
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 20:33:26
Query 'Data is required. Please complete.' answered with 'NA' (Site from System).	(b) (4), (b) (6)	10 Nov 2020 20:15:08
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 20:14:47
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 20:14:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 20:13:14

**US3312637**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 17:06:05**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 20:13:14

**US3312637**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 17:06:05**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:48:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '0'	(b) (4), (b) (6)	10 Nov 2020 20:13:14

US3312637

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:06:05

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered 'Jan 2018'	System	10 Nov 2020 20:33:26
User entered empty.	System	10 Nov 2020 20:14:47
User entered 'Sep 2020'	System	10 Nov 2020 20:13:14

US3312637

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:06:05

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered '2018'	System	10 Nov 2020 20:33:26
User entered empty.	System	10 Nov 2020 20:14:47
User entered '2020'	System	10 Nov 2020 20:13:14



**US3312637**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 17:06:05**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered empty.	System	10 Nov 2020 20:13:14

**US3312637**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 17:06:05**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered empty.	System	10 Nov 2020 20:13:14

US3312637

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:41:49
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Yes (Y)'	Karol Moore (b) (4)	30 Sep 2020 23:18:02

US3312637

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:41:49
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '11 Sep 2020'	Karol Moore (b) (4)	30 Sep 2020 23:18:02

US3312637

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:41:49
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '14:07'	Karol Moore (b) (4)	30 Sep 2020 23:18:02

**US3312637**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:06:05**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered '11 Sep 2020 14:07'	System	30 Sep 2020 23:18:02

US3312637

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:05

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:41:49
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '69' in	Karol Moore (b) (4)	30 Sep 2020 23:18:02
DataPoint set to visible.	System	11 Sep 2020 20:38:50

US3312637

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:05

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:41:49
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '233' lb	Karol Moore (b) (4)	30 Sep 2020 23:18:02
DataPoint set to visible.	System	11 Sep 2020 20:38:50



US3312637

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:05

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered '34.48003'	System	30 Sep 2020 23:18:02
DataPoint set to visible.	System	11 Sep 2020 20:38:50

**US3312637**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:06:05**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered 'kg/m2'	System	30 Sep 2020 23:18:02
DataPoint set to visible.	System	11 Sep 2020 20:38:50

US3312637

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:41:49
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered missing code ND - Not Done.	Karol Moore (b) (4)	30 Sep 2020 23:18:02

US3312637

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:41:49
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Oral (Oral)'	Karol Moore (b) (4)	30 Sep 2020 23:18:02

US3312637

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:41:49
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered empty.	Karol Moore (b) (4)	30 Sep 2020 23:18:02

US3312637

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:41:49
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered missing code ND - Not Done.	Karol Moore (b) (4)	30 Sep 2020 23:18:02

**US3312637**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:06:05**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered 'bpm'	System	30 Sep 2020 23:18:02

US3312637

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:41:49
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered missing code ND - Not Done.	Karol Moore (b) (4)	30 Sep 2020 23:18:02



US3312637

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered 'breaths/min'	System	30 Sep 2020 23:18:02

US3312637

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:41:49
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered missing code ND - Not Done.	Karol Moore (b) (4)	30 Sep 2020 23:18:02

US3312637

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered 'mmHg'	System	30 Sep 2020 23:18:02

US3312637

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:41:49
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered missing code ND - Not Done.	Karol Moore (b) (4)	30 Sep 2020 23:18:02

US3312637

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered 'mmHg'	System	30 Sep 2020 23:18:02

US3312637

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:05

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:05

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04

US3312637

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:06:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:41:59
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Yes (Y)'	Karol Moore (b) (4)	30 Sep 2020 23:18:12



US3312637

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:06:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:41:59
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '11 Sep 2020'	Karol Moore (b) (4)	30 Sep 2020 23:18:12

US3312637

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:05

**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 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:43:58
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'No (N)'	Karol Moore (b) (4)	30 Sep 2020 23:18:40

US3312637

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:05

**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 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:43:58
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'No (N)'	Karol Moore (b) (4)	30 Sep 2020 23:18:40

US3312637

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:05

**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 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:43:58
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'No (N)'	Karol Moore (b) (4)	30 Sep 2020 23:18:40

US3312637

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:05

**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 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:43:58
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'No (N)'	Karol Moore (b) (4)	30 Sep 2020 23:18:40

US3312637

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:05

[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 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:43:58
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'No (N)'	Karol Moore (b) (4)	30 Sep 2020 23:18:40

US3312637

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:05

[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 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:43:58
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'No (N)'	Karol Moore (b) (4)	30 Sep 2020 23:18:40

US3312637

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:05

**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 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:43:58
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'No (N)'	Karol Moore (b) (4)	30 Sep 2020 23:18:40



US3312637

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:05

**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 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:43:58
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'No (N)'	Karol Moore (b) (4)	30 Sep 2020 23:18:40

US3312637

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:05

[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 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:43:58
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'No (N)'	Karol Moore (b) (4)	30 Sep 2020 23:18:40

US3312637

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:05

**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 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:43:58
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'No (N)'	Karol Moore (b) (4)	30 Sep 2020 23:18:40

US3312637

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:05

**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 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:43:58
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'No (N)'	Karol Moore (b) (4)	30 Sep 2020 23:18:40

US3312637

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:05

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:43:58
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'No (N)'	Karol Moore (b) (4)	30 Sep 2020 23:18:40

US3312637

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:05

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:43:58
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered empty.	Karol Moore (b) (4)	30 Sep 2020 23:18:40

US3312637

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:05

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '0'	Karol Moore (b) (4)	30 Sep 2020 23:18:40

US3312637

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:05

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:43:58
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '0'	Karol Moore (b) (4)	30 Sep 2020 23:18:40



US3312637

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:05

**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 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:43:58
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '0'	Karol Moore (b) (4)	30 Sep 2020 23:18:40

US3312637

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:05

[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 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:43:58
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'l'	Karol Moore (b) (4)	30 Sep 2020 23:18:40

US3312637

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:05

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 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:43:58
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '0'	Karol Moore (b) (4)	30 Sep 2020 23:18:40

US3312637

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:05

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:43:58
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '0'	Karol Moore (b) (4)	30 Sep 2020 23:18:40

US3312637

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:05

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '0'	Karol Moore (b) (4)	30 Sep 2020 23:18:40

US3312637

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:05

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:43:58
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered empty.	Karol Moore (b) (4)	30 Sep 2020 23:18:40

US3312637

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:06:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:41:52
User entered 'Yes (Y)'	Christa Estrada (b) (4)	11 Sep 2020 20:39:05

**US3312637**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:06:05**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:41:52
User entered '11 Sep 2020'	Christa Estrada (b) (4)	11 Sep 2020 20:39:05



US3312637

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:06:05

[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 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:41:52
User entered 'Clinic (Clinic)'	Christa Estrada (b) (4)	11 Sep 2020 20:39:05

US3312637

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:06:05

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered 'VISIT1'	System	11 Sep 2020 20:39:05

US3312637

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:06:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:42:33
User entered '11 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 20:14:29

US3312637

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:06:05

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:42:33
User entered '146256'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 20:14:29

US3312637

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:06:05

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:42:33
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 20:14:29

US3312637

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:06:05

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 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:42:33
User entered 'Yes (Y)'	Christa Estrada (b) (4)	11 Sep 2020 20:39:20

US3312637

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:06:05

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 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:42:33
User entered 'No (N)'	Christa Estrada (b) (4)	11 Sep 2020 20:39:20

US3312637

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:06:05

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:42:33
User entered 'No (N)'	Christa Estrada (b) (4)	11 Sep 2020 20:39:20



US3312637

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:06:05

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:42:33
User entered 'No (N)'	Christa Estrada (b) (4)	11 Sep 2020 20:39:20

US3312637

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:06:05

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:42:33
User entered 'No (N)'	Christa Estrada (b) (4)	11 Sep 2020 20:39:20

US3312637

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:06:05

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:42:33
User entered 'No (N)'	Karol Moore (b) (4)	30 Sep 2020 23:18:49
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 06:14:30
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:14:29

US3312637

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:06:05

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:56:20
User entered missing code ND - Not Done.	Karol Moore (b) (4)	30 Sep 2020 23:19:39

US3312637

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:06:05

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:56:20
User entered missing code ND - Not Done.	Karol Moore (b) (4)	30 Sep 2020 23:19:39

US3312637

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:06:05

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:56:20
User entered missing code ND - Not Done.	Karol Moore (b) (4)	30 Sep 2020 23:19:39

US3312637

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:06:05

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:56:20
User entered missing code ND - Not Done.	Karol Moore (b) (4)	30 Sep 2020 23:19:39

US3312637

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User accepted default value 'Pre-Dose (PREDOSE)'	Karol Moore (b) (4)	30 Sep 2020 23:19:39



US3312637

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:56:20
User entered 'Yes (Y)'	Karol Moore (b) (4)	30 Sep 2020 23:19:39

US3312637

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:56:20
User entered '11 Sep 2020'	Karol Moore (b) (4)	30 Sep 2020 23:19:39

US3312637

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:56:20
User entered '14:07'	Karol Moore (b) (4)	30 Sep 2020 23:19:39

US3312637

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered '11 Sep 2020 14:07'	System	30 Sep 2020 23:19:39

US3312637

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:56:20
User entered '98.0' F	Karol Moore (b) (4)	30 Sep 2020 23:19:39

US3312637

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:56:20
User entered 'Oral (Oral)'	Karol Moore (b) (4)	30 Sep 2020 23:19:39

US3312637

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:56:20
User entered empty.	Karol Moore (b) (4)	30 Sep 2020 23:19:39

US3312637

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:56:20
User entered '72'	Karol Moore (b) (4)	30 Sep 2020 23:19:39



US3312637

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered 'bpm'	System	30 Sep 2020 23:19:39

US3312637

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:56:20
User entered '16'	Karol Moore (b) (4)	30 Sep 2020 23:19:39

US3312637

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered 'breaths/min'	System	30 Sep 2020 23:19:39

US3312637

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:56:20
User entered '140'	Karol Moore (b) (4)	30 Sep 2020 23:19:39

US3312637

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered 'mmHg'	System	30 Sep 2020 23:19:39

US3312637

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:56:20
User entered '87'	Karol Moore (b) (4)	30 Sep 2020 23:19:39

US3312637

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered 'mmHg'	System	30 Sep 2020 23:19:39

US3312637

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:06:05

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:56:20
User entered missing code ND - Not Done.	Karol Moore (b) (4)	30 Sep 2020 23:19:39



US3312637

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:06:05

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:56:20
User entered missing code ND - Not Done.	Karol Moore (b) (4)	30 Sep 2020 23:19:39

US3312637

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User accepted default value 'Post-Dose (POSTDOSE)'	Karol Moore (b) (4)	30 Sep 2020 23:19:39

US3312637

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:56:20
User entered 'Yes (Y)'	Karol Moore (b) (4)	30 Sep 2020 23:19:39

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:56:20
User entered '11 Sep 2020'	Karol Moore (b) (4)	30 Sep 2020 23:19:39

US3312637

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:56:20
User entered '16:06'	Karol Moore (b) (4)	30 Sep 2020 23:19:39

US3312637

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered '11 Sep 2020 16:06'	System	30 Sep 2020 23:19:39

US3312637

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:56:20
User entered '98.9' F	Karol Moore (b) (4)	30 Sep 2020 23:19:39

US3312637

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:56:20
User entered 'Oral (Oral)'	Karol Moore (b) (4)	30 Sep 2020 23:19:39



US3312637

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:56:20
User entered empty.	Karol Moore (b) (4)	30 Sep 2020 23:19:39

US3312637

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:56:20
User entered '68'	Karol Moore (b) (4)	30 Sep 2020 23:19:39

US3312637

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered 'bpm'	System	30 Sep 2020 23:19:39

US3312637

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:56:20
User entered '16'	Karol Moore (b) (4)	30 Sep 2020 23:19:39

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered 'breaths/min'	System	30 Sep 2020 23:19:39

US3312637

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:56:20
User entered '135'	Karol Moore (b) (4)	30 Sep 2020 23:19:39

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered 'mmHg'	System	30 Sep 2020 23:19:39

US3312637

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:56:20
User entered '78'	Karol Moore (b) (4)	30 Sep 2020 23:19:39



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered 'mmHg'	System	30 Sep 2020 23:19:39

US3312637

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:06:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:56:29
User entered 'No (N)'	Karol Moore (b) (4)	30 Sep 2020 23:19:50

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:06:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:56:29
User entered empty.	Karol Moore (b) (4)	30 Sep 2020 23:19:50

US3312637

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:06:05

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:57:28
User entered 'Yes (Y)'	Christa Estrada (b) (4)	11 Sep 2020 20:39:45

US3312637

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:06:05

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:57:28
User entered empty.	Christa Estrada (b) (4)	11 Sep 2020 20:39:45

US3312637

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:06:05

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 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:57:28
User entered empty.	Christa Estrada (b) (4)	11 Sep 2020 20:39:45

US3312637

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:06:05

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered 'MRNA-1273 OR PLACEBO'	System	11 Sep 2020 20:39:45

US3312637

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:06:05

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:57:28
User entered '11 Sep 2020'	Christa Estrada (b) (4)	11 Sep 2020 20:39:45



US3312637

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:06:05

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:57:28
User entered '15:35'	Christa Estrada (b) (4)	11 Sep 2020 20:39:45

US3312637

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:06:05

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered '11 Sep 2020 15:35'	System	11 Sep 2020 20:39:45

US3312637

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:06:05

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:57:28
User entered 'Left Arm (LEFT ARM)'	Christa Estrada (b) (4)	11 Sep 2020 20:39:45

US3312637

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:06:05

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:57:28
User entered 'ONCE'	System	11 Sep 2020 20:39:45

US3312637

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:06:05

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered 'INTRAMUSCULAR'	System	11 Sep 2020 20:39:45

US3312637

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:57:42
User entered 'Yes (Y)'	Karol Moore (b) (4)	30 Sep 2020 23:20:10

US3312637

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:05

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:57:42
User entered '11 Sep 2020'	Karol Moore (b) (4)	30 Sep 2020 23:20:10

US3312637

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:05

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:57:42
User entered '14:59'	Karol Moore (b) (4)	30 Sep 2020 23:20:10



**US3312637**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:06:05**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered '11 Sep 2020 14:59'	System	30 Sep 2020 23:20:10

US3312637

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:06:05

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:57:52
User entered '11 Sep 2020'	Karol Moore (b) (4)	30 Sep 2020 23:20:22

US3312637

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:06:05

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Karol Moore (b) (4)	30 Sep 2020 23:20:22

US3312637

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:06:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:57:52
User entered 'Yes (Y)'	Karol Moore (b) (4)	30 Sep 2020 23:20:22

**US3312637**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:06:05**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:57:52
User entered '14:51'	Karol Moore (b) (4)	30 Sep 2020 23:20:22

**US3312637**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:06:05**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered '11 Sep 2020 14:51'	System	30 Sep 2020 23:20:22

US3312637

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:06:05

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Karol Moore (b) (4)	30 Sep 2020 23:20:22

US3312637

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:06:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:57:52
User entered 'No (N)'	Karol Moore (b) (4)	30 Sep 2020 23:20:22



US3312637

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:06:05

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:57:52
User entered empty.	Karol Moore (b) (4)	30 Sep 2020 23:20:22

US3312637

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:06:05

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered empty.	System	30 Sep 2020 23:20:22

US3312637

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:06:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:58:13
User entered 'Yes (Y)'	Karol Moore (b) (4)	30 Sep 2020 23:20:25

US3312637

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:06:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered 'I'	System	30 Sep 2020 23:20:25

US3312637

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:06:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
Data entry locked.	System	11 Sep 2020 20:39:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 20:39:45

US3312637

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:06:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-11T16:08:43', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '260765bb-be1f-4179-a6e9-05c195aa7c7e'	System	11 Sep 2020 21:09:06
User entered 'Yes (Y)'	System	11 Sep 2020 21:09:06

US3312637

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:06:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-11T16:08:52', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '260765bb-be1f-4179-a6e9-05c195aa7c7e'	System	11 Sep 2020 21:09:06
User entered '98.9'	System	11 Sep 2020 21:09:06

US3312637

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:06:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-11T16:08:57', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '260765bb-be1f-4179-a6e9-05c195aa7c7e'	System	11 Sep 2020 21:09:06
User entered 'No (N)'	System	11 Sep 2020 21:09:06



US3312637

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:06:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-11T16:09:04', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '260765bb-be1f-4179-a6e9-05c195aa7c7e'	System	11 Sep 2020 21:09:06
User entered '11 Sep 2020 16:09'	System	11 Sep 2020 21:09:06

US3312637

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:06:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
User entered '11 Sep 2020 15:55'	System	11 Sep 2020 20:39:45

US3312637

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:06:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
User entered '11 Sep 2020 18:25'	System	11 Sep 2020 20:39:45

US3312637

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:06:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
Data entry locked.	System	11 Sep 2020 20:39:45
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 20:39:45

US3312637

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:06:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-11T23:12:15', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'bef1bbd3-afc8-4b82-ae47-4b3bf05fd1f8'	System	12 Sep 2020 04:12:42
User entered 'Yes (Y)'	System	12 Sep 2020 04:12:42

US3312637

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:06:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-11T23:12:26', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'bef1bbd3-afc8-4b82-ae47-4b3bf05fd1f8'	System	12 Sep 2020 04:12:42
User entered '98.1'	System	12 Sep 2020 04:12:42

US3312637

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:06:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-11T23:12:31', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'bef1bbd3-afc8-4b82-ae47-4b3bf05fd1f8'	System	12 Sep 2020 04:12:42
User entered 'No (N)'	System	12 Sep 2020 04:12:42

US3312637

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:06:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-11T23:12:36', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'bef1bbd3-afc8-4b82-ae47-4b3bf05fd1f8'	System	12 Sep 2020 04:12:42
User entered '11 Sep 2020 23:12'	System	12 Sep 2020 04:12:42



US3312637

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:06:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
User entered '11 Sep 2020 19:20'	System	11 Sep 2020 20:39:45

US3312637

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:06:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 20:39:45

US3312637

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:06:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
Data entry locked.	System	11 Sep 2020 20:39:45
User entered 'Day 2'	System	11 Sep 2020 20:39:45

US3312637

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:06:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-12T15:34:19', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'b70ba3bf-c6ea-4f0c-80c0-42811e30307a'	System	12 Sep 2020 20:36:05
User entered 'Yes (Y)'	System	12 Sep 2020 20:36:05

US3312637

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:06:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-12T15:35:51', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'b70ba3bf-c6ea-4f0c-80c0-42811e30307a'	System	12 Sep 2020 20:36:05
User entered '97.9'	System	12 Sep 2020 20:36:05

US3312637

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:06:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-12T15:35:58', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'b70ba3bf-c6ea-4f0c-80c0-42811e30307a'	System	12 Sep 2020 20:36:05
User entered 'No (N)'	System	12 Sep 2020 20:36:05

US3312637

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:06:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-12T15:36:03', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'b70ba3bf-c6ea-4f0c-80c0-42811e30307a'	System	12 Sep 2020 20:36:05
User entered '12 Sep 2020 15:36'	System	12 Sep 2020 20:36:05

US3312637

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:06:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 20:39:45



US3312637

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:06:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 20:39:45

US3312637

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:06:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
Data entry locked.	System	11 Sep 2020 20:39:45
User entered 'Day 3'	System	11 Sep 2020 20:39:45

US3312637

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:06:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-13T20:58:57', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'eb4c917d-38f7-4127-87af-21282eb35bfc'	System	14 Sep 2020 01:59:19
User entered 'Yes (Y)'	System	14 Sep 2020 01:59:19

US3312637

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:06:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-13T20:59:06', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'eb4c917d-38f7-4127-87af-21282eb35bfc'	System	14 Sep 2020 01:59:19
User entered '98.3'	System	14 Sep 2020 01:59:19

US3312637

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:06:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-13T20:59:12', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'eb4c917d-38f7-4127-87af-21282eb35bfc'	System	14 Sep 2020 01:59:19
User entered 'No (N)'	System	14 Sep 2020 01:59:19

US3312637

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:06:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-13T20:59:16', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'eb4c917d-38f7-4127-87af-21282eb35bfc'	System	14 Sep 2020 01:59:19
User entered '13 Sep 2020 20:59'	System	14 Sep 2020 01:59:19

US3312637

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:06:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 20:39:45

US3312637

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:06:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 20:39:45



US3312637

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:06:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
Data entry locked.	System	11 Sep 2020 20:39:45
User entered 'Day 4'	System	11 Sep 2020 20:39:45

US3312637

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:06:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-14T13:19:52', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '8bf7978a-5de3-4481-92fb-b5c22dafa7ec'	System	14 Sep 2020 18:20:26
User entered 'Yes (Y)'	System	14 Sep 2020 18:20:26

US3312637

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:06:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-14T13:20:12', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '8bf7978a-5de3-4481-92fb-b5c22dfe7ec'	System	14 Sep 2020 18:20:26
User entered '98.1'	System	14 Sep 2020 18:20:26

US3312637

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:06:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-14T13:20:19', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '8bf7978a-5de3-4481-92fb-b5c22dafa7ec'	System	14 Sep 2020 18:20:26
User entered 'No (N)'	System	14 Sep 2020 18:20:26

US3312637

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:06:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-14T13:20:24', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '8bf7978a-5de3-4481-92fb-b5c22dafa7ec'	System	14 Sep 2020 18:20:26
User entered '14 Sep 2020 13:20'	System	14 Sep 2020 18:20:26

US3312637

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:06:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 20:39:45

US3312637

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:06:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 20:39:45

US3312637

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:06:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
Data entry locked.	System	11 Sep 2020 20:39:45
User entered 'Day 5'	System	11 Sep 2020 20:39:45



US3312637

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:06:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-15T12:09:11', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'c879dad1-8dae-409e-8187-f561c8f02cf0'	System	15 Sep 2020 17:09:39
User entered 'Yes (Y)'	System	15 Sep 2020 17:09:39

US3312637

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:06:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-15T12:09:20', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'c879dad1-8dae-409e-8187-f561c8f02cf0'	System	15 Sep 2020 17:09:39
User entered '97.1'	System	15 Sep 2020 17:09:39

US3312637

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:06:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-15T12:09:25', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'c879dad1-8dae-409e-8187-f561c8f02cf0'	System	15 Sep 2020 17:09:39
User entered 'No (N)'	System	15 Sep 2020 17:09:39

US3312637

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:06:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-15T12:09:28', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'c879dad1-8dae-409e-8187-f561c8f02cf0'	System	15 Sep 2020 17:09:39
User entered '15 Sep 2020 12:09'	System	15 Sep 2020 17:09:39

US3312637

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:06:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 20:39:45

US3312637

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:06:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 20:39:45

US3312637

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:06:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
Data entry locked.	System	11 Sep 2020 20:39:45
User entered 'Day 6'	System	11 Sep 2020 20:39:45

US3312637

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:06:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-16T13:05:02', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'f2631531-c36d-42cd-81f4-d26480a51875'	System	16 Sep 2020 18:05:23
User entered 'Yes (Y)'	System	16 Sep 2020 18:05:23



US3312637

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:06:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-16T13:05:13', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'f2631531-c36d-42cd-81f4-d26480a51875'	System	16 Sep 2020 18:05:23
User entered '97.4'	System	16 Sep 2020 18:05:23

US3312637

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:06:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-16T13:05:19', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'f2631531-c36d-42cd-81f4-d26480a51875'	System	16 Sep 2020 18:05:23
User entered 'No (N)'	System	16 Sep 2020 18:05:23

US3312637

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:06:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-16T13:05:23', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'f2631531-c36d-42cd-81f4-d26480a51875'	System	16 Sep 2020 18:05:23
User entered '16 Sep 2020 13:05'	System	16 Sep 2020 18:05:23

US3312637

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:06:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 20:39:45

US3312637

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:06:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 20:39:45

US3312637

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:06:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
Data entry locked.	System	11 Sep 2020 20:39:45
User entered 'Day 7'	System	11 Sep 2020 20:39:45

US3312637

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:06:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-17T18:33:11', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '2ebe25b4-66e4-4c02-a4d2-6bc93d812e42'	System	17 Sep 2020 23:33:33
User entered 'Yes (Y)'	System	17 Sep 2020 23:33:33

US3312637

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:06:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-17T18:33:19', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '2ebe25b4-66e4-4c02-a4d2-6bc93d812e42'	System	17 Sep 2020 23:33:33
User entered '98.8'	System	17 Sep 2020 23:33:33



US3312637

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:06:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-17T18:33:23', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '2ebe25b4-66e4-4c02-a4d2-6bc93d812e42'	System	17 Sep 2020 23:33:33
User entered 'No (N)'	System	17 Sep 2020 23:33:33

US3312637

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:06:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-17T18:33:27', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '2ebe25b4-66e4-4c02-a4d2-6bc93d812e42'	System	17 Sep 2020 23:33:33
User entered '17 Sep 2020 18:33'	System	17 Sep 2020 23:33:33

US3312637

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:06:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 20:39:45

US3312637

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:06:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 20:39:45

US3312637

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:06:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
Data entry locked.	System	11 Sep 2020 20:39:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 20:39:45

US3312637

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:06:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-11T16:09:15', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '8e1cd6be-1c85-48fc-b730-11112ce1b420'	System	11 Sep 2020 21:09:47
User entered 'None (1)'	System	11 Sep 2020 21:09:47

US3312637

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:06:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-11T16:09:19', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '8e1cd6be-1c85-48fc-b730-11112ce1b420'	System	11 Sep 2020 21:09:47
User entered 'No (N)'	System	11 Sep 2020 21:09:47

US3312637

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:06:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-11T16:09:23', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '8e1cd6be-1c85-48fc-b730-11112ce1b420'	System	11 Sep 2020 21:09:47
User entered 'No (N)'	System	11 Sep 2020 21:09:47



US3312637

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:06:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-11T16:09:28', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '8e1cd6be-1c85-48fc-b730-11112ce1b420'	System	11 Sep 2020 21:09:47
User entered 'None (1)'	System	11 Sep 2020 21:09:47

US3312637

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:06:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-11T16:09:38', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '8e1cd6be-1c85-48fc-b730-11112ce1b420'	System	11 Sep 2020 21:09:47
User entered '11 Sep 2020 16:09'	System	11 Sep 2020 21:09:47

US3312637

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:06:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
User entered '11 Sep 2020 15:55'	System	11 Sep 2020 20:39:45

US3312637

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:06:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
User entered '11 Sep 2020 18:25'	System	11 Sep 2020 20:39:45

US3312637

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:06:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
Data entry locked.	System	11 Sep 2020 20:39:45
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 20:39:45

US3312637

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:06:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-11T23:12:52', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '03f8ab77-d448-4f0b-9874-cb6fadc6d821'	System	12 Sep 2020 04:13:19
User entered 'None (1)'	System	12 Sep 2020 04:13:19

US3312637

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:06:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-11T23:12:56', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '03f8ab77-d448-4f0b-9874-cb6fadc6d821'	System	12 Sep 2020 04:13:19
User entered 'No (N)'	System	12 Sep 2020 04:13:19

US3312637

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:06:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-11T23:13:00', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '03f8ab77-d448-4f0b-9874-cb6fadc6d821'	System	12 Sep 2020 04:13:19
User entered 'No (N)'	System	12 Sep 2020 04:13:19



US3312637

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:06:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-11T23:13:13', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '03f8ab77-d448-4f0b-9874-cb6fadc6d821'	System	12 Sep 2020 04:13:19
User entered 'None (1)'	System	12 Sep 2020 04:13:19

US3312637

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:06:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-11T23:13:17', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '03f8ab77-d448-4f0b-9874-cb6fadc6d821'	System	12 Sep 2020 04:13:19
User entered '11 Sep 2020 23:13'	System	12 Sep 2020 04:13:19

US3312637

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:06:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
User entered '11 Sep 2020 19:20'	System	11 Sep 2020 20:39:45

US3312637

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:06:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 20:39:45

US3312637

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:06:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
Data entry locked.	System	11 Sep 2020 20:39:45
User entered 'Day 2'	System	11 Sep 2020 20:39:45

US3312637

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:06:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-12T15:36:09', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '3843c6bb-18ff-46c3-afe0-6de3fcb8dbf5'	System	12 Sep 2020 20:36:33
User entered 'None (1)'	System	12 Sep 2020 20:36:33

US3312637

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:06:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-12T15:36:14', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '3843c6bb-18ff-46c3-afe0-6de3fcb8dbf5'	System	12 Sep 2020 20:36:33
User entered 'No (N)'	System	12 Sep 2020 20:36:33

US3312637

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:06:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-12T15:36:17', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '3843c6bb-18ff-46c3-afe0-6de3fcb8dbf5'	System	12 Sep 2020 20:36:33
User entered 'No (N)'	System	12 Sep 2020 20:36:33



US3312637

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:06:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-12T15:36:23', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '3843c6bb-18ff-46c3-afe0-6de3fcb8dbf5'	System	12 Sep 2020 20:36:33
User entered 'None (1)'	System	12 Sep 2020 20:36:33

US3312637

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:06:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-12T15:36:29', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '3843c6bb-18ff-46c3-afe0-6de3fcb8dbf5'	System	12 Sep 2020 20:36:33
User entered '12 Sep 2020 15:36'	System	12 Sep 2020 20:36:33

US3312637

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:06:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 20:39:45

US3312637

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:06:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 20:39:45

US3312637

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:06:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
Data entry locked.	System	11 Sep 2020 20:39:45
User entered 'Day 3'	System	11 Sep 2020 20:39:45

US3312637

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:06:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-13T20:59:24', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'b9286235-e940-47d0-9b35-e99f588686cc'	System	14 Sep 2020 01:59:56
User entered 'None (1)'	System	14 Sep 2020 01:59:56

US3312637

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:06:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-13T20:59:28', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'b9286235-e940-47d0-9b35-e99f588686cc'	System	14 Sep 2020 01:59:56
User entered 'No (N)'	System	14 Sep 2020 01:59:56

US3312637

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:06:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-13T20:59:35', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'b9286235-e940-47d0-9b35-e99f588686cc'	System	14 Sep 2020 01:59:56
User entered 'No (N)'	System	14 Sep 2020 01:59:56



US3312637

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:06:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-13T20:59:50', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'b9286235-e940-47d0-9b35-e99f588686cc'	System	14 Sep 2020 01:59:56
User entered 'None (1)'	System	14 Sep 2020 01:59:56

US3312637

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:06:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-13T20:59:54', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'b9286235-e940-47d0-9b35-e99f588686cc'	System	14 Sep 2020 01:59:56
User entered '13 Sep 2020 20:59'	System	14 Sep 2020 01:59:56

US3312637

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:06:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 20:39:45

US3312637

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:06:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 20:39:45

US3312637

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:06:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
Data entry locked.	System	11 Sep 2020 20:39:45
User entered 'Day 4'	System	11 Sep 2020 20:39:45

US3312637

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:06:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-14T13:20:30', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '0d0fcd9b-eb98-4ee8-9f0a-291476476b34'	System	14 Sep 2020 18:20:45
User entered 'None (1)'	System	14 Sep 2020 18:20:45

US3312637

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:06:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-14T13:20:34', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '0d0fcd9b-eb98-4ee8-9f0a-291476476b34'	System	14 Sep 2020 18:20:45
User entered 'No (N)'	System	14 Sep 2020 18:20:45

US3312637

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:06:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-14T13:20:37', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '0d0fcd9b-eb98-4ee8-9f0a-291476476b34'	System	14 Sep 2020 18:20:45
User entered 'No (N)'	System	14 Sep 2020 18:20:45



US3312637

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:06:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-14T13:20:41', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '0d0fcd9b-eb98-4ee8-9f0a-291476476b34'	System	14 Sep 2020 18:20:45
User entered 'None (1)'	System	14 Sep 2020 18:20:45

US3312637

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:06:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-14T13:20:43', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '0d0fcd9b-eb98-4ee8-9f0a-291476476b34'	System	14 Sep 2020 18:20:45
User entered '14 Sep 2020 13:20'	System	14 Sep 2020 18:20:45

US3312637

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:06:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 20:39:45

US3312637

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:06:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 20:39:45

US3312637

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:06:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
Data entry locked.	System	11 Sep 2020 20:39:45
User entered 'Day 5'	System	11 Sep 2020 20:39:45

US3312637

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:06:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-15T12:09:33', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '37f506d4-3f25-475b-acf5-efbe4f3d7fa1'	System	15 Sep 2020 17:09:50
User entered 'None (1)'	System	15 Sep 2020 17:09:50

US3312637

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:06:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-15T12:09:37', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '37f506d4-3f25-475b-acf5-efbe4f3d7fa1'	System	15 Sep 2020 17:09:50
User entered 'No (N)'	System	15 Sep 2020 17:09:50

US3312637

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:06:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-15T12:09:40', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '37f506d4-3f25-475b-acf5-efbe4f3d7fa1'	System	15 Sep 2020 17:09:50
User entered 'No (N)'	System	15 Sep 2020 17:09:50



US3312637

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:06:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-15T12:09:44', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '37f506d4-3f25-475b-acf5-efbe4f3d7fa1'	System	15 Sep 2020 17:09:50
User entered 'None (1)'	System	15 Sep 2020 17:09:50

US3312637

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:06:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-15T12:09:48', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '37f506d4-3f25-475b-acf5-efbe4f3d7fa1'	System	15 Sep 2020 17:09:50
User entered '15 Sep 2020 12:09'	System	15 Sep 2020 17:09:50

US3312637

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:06:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 20:39:45

US3312637

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:06:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 20:39:45

US3312637

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:06:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
Data entry locked.	System	11 Sep 2020 20:39:45
User entered 'Day 6'	System	11 Sep 2020 20:39:45

US3312637

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:06:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-16T13:05:32', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '1070b25b-7413-41a2-afdc-41af2ee52ab2'	System	16 Sep 2020 18:05:48
User entered 'None (1)'	System	16 Sep 2020 18:05:48

US3312637

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:06:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-16T13:05:36', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '1070b25b-7413-41a2-afdc-41af2ee52ab2'	System	16 Sep 2020 18:05:48
User entered 'No (N)'	System	16 Sep 2020 18:05:48

US3312637

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:06:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-16T13:05:39', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '1070b25b-7413-41a2-afdc-41af2ee52ab2'	System	16 Sep 2020 18:05:48
User entered 'No (N)'	System	16 Sep 2020 18:05:48



US3312637

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:06:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-16T13:05:43', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '1070b25b-7413-41a2-afdc-41af2ee52ab2'	System	16 Sep 2020 18:05:48
User entered 'None (1)'	System	16 Sep 2020 18:05:48

US3312637

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:06:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-16T13:05:46', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '1070b25b-7413-41a2-afdc-41af2ee52ab2'	System	16 Sep 2020 18:05:48
User entered '16 Sep 2020 13:05'	System	16 Sep 2020 18:05:48

US3312637

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:06:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 20:39:45

US3312637

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:06:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 20:39:45

US3312637

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:06:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
Data entry locked.	System	11 Sep 2020 20:39:45
User entered 'Day 7'	System	11 Sep 2020 20:39:45

US3312637

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:06:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-17T18:33:31', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '339d571e-831b-4c18-8e50-d8eca37b6554'	System	17 Sep 2020 23:33:45
User entered 'None (1)'	System	17 Sep 2020 23:33:45

US3312637

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:06:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-17T18:33:35', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '339d571e-831b-4c18-8e50-d8eca37b6554'	System	17 Sep 2020 23:33:45
User entered 'No (N)'	System	17 Sep 2020 23:33:45

US3312637

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:06:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-17T18:33:37', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '339d571e-831b-4c18-8e50-d8eca37b6554'	System	17 Sep 2020 23:33:45
User entered 'No (N)'	System	17 Sep 2020 23:33:45



US3312637

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:06:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-17T18:33:41', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '339d571e-831b-4c18-8e50-d8eca37b6554'	System	17 Sep 2020 23:33:45
User entered 'None (1)'	System	17 Sep 2020 23:33:45

US3312637

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:06:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-17T18:33:44', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '339d571e-831b-4c18-8e50-d8eca37b6554'	System	17 Sep 2020 23:33:45
User entered '17 Sep 2020 18:33'	System	17 Sep 2020 23:33:45

US3312637

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:06:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 20:39:45

US3312637

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:06:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 20:39:45

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:06:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
Data entry locked.	System	11 Sep 2020 20:39:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 20:39:45

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:06:05

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-11T16:09:45', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '428188ff-637e-4d85-9e47-16c628f9ac6d'	System	11 Sep 2020 21:10:18
User entered 'None (0)'	System	11 Sep 2020 21:10:18

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:06:05

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-11T16:09:49', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '428188ff-637e-4d85-9e47-16c628f9ac6d'	System	11 Sep 2020 21:10:18
User entered 'None (0)'	System	11 Sep 2020 21:10:18

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:06:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-11T16:09:54', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '428188ff-637e-4d85-9e47-16c628f9ac6d'	System	11 Sep 2020 21:10:18
User entered 'None (0)'	System	11 Sep 2020 21:10:18



US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:06:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-11T16:09:58', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '428188ff-637e-4d85-9e47-16c628f9ac6d'	System	11 Sep 2020 21:10:18
User entered 'None (0)'	System	11 Sep 2020 21:10:18

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:06:05

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-11T16:10:04', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '428188ff-637e-4d85-9e47-16c628f9ac6d'	System	11 Sep 2020 21:10:18
User entered 'None (0)'	System	11 Sep 2020 21:10:18

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:06:05

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-11T16:10:08', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '428188ff-637e-4d85-9e47-16c628f9ac6d'	System	11 Sep 2020 21:10:18
User entered 'None (0)'	System	11 Sep 2020 21:10:18

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:06:05

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)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-11T16:10:13', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '428188ff-637e-4d85-9e47-16c628f9ac6d'	System	11 Sep 2020 21:10:18
User entered 'No (N)'	System	11 Sep 2020 21:10:18

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:06:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-11T16:10:17', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '428188ff-637e-4d85-9e47-16c628f9ac6d'	System	11 Sep 2020 21:10:18
User entered '11 Sep 2020 16:10'	System	11 Sep 2020 21:10:18

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:06:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
User entered '11 Sep 2020 15:55'	System	11 Sep 2020 20:39:45

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:06:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
User entered '11 Sep 2020 18:25'	System	11 Sep 2020 20:39:45

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:06:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
Data entry locked.	System	11 Sep 2020 20:39:45
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 20:39:45



US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:06:05

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-11T23:13:23', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'c1f149e2-18a8-402e-ad9d-f213f8d6e555'	System	12 Sep 2020 04:13:51
User entered 'None (0)'	System	12 Sep 2020 04:13:51

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:06:05

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-11T23:13:27', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'c1f149e2-18a8-402e-ad9d-f213f8d6e555'	System	12 Sep 2020 04:13:51
User entered 'None (0)'	System	12 Sep 2020 04:13:51

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:06:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-11T23:13:31', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'c1f149e2-18a8-402e-ad9d-f213f8d6e555'	System	12 Sep 2020 04:13:51
User entered 'None (0)'	System	12 Sep 2020 04:13:51

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:06:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-11T23:13:34', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'c1f149e2-18a8-402e-ad9d-f213f8d6e555'	System	12 Sep 2020 04:13:51
User entered 'None (0)'	System	12 Sep 2020 04:13:51

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:06:05

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-11T23:13:38', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'c1f149e2-18a8-402e-ad9d-f213f8d6e555'	System	12 Sep 2020 04:13:51
User entered 'None (0)'	System	12 Sep 2020 04:13:51

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:06:05

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-11T23:13:41', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'c1f149e2-18a8-402e-ad9d-f213f8d6e555'	System	12 Sep 2020 04:13:51
User entered 'None (0)'	System	12 Sep 2020 04:13:51

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:06:05

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)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-11T23:13:46', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'c1f149e2-18a8-402e-ad9d-f213f8d6e555'	System	12 Sep 2020 04:13:51
User entered 'No (N)'	System	12 Sep 2020 04:13:51

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:06:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-11T23:13:50', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'c1f149e2-18a8-402e-ad9d-f213f8d6e555'	System	12 Sep 2020 04:13:51
User entered '11 Sep 2020 23:13'	System	12 Sep 2020 04:13:51



US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:06:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
User entered '11 Sep 2020 19:20'	System	11 Sep 2020 20:39:45

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:06:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 20:39:45

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:06:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
Data entry locked.	System	11 Sep 2020 20:39:45
User entered 'Day 2'	System	11 Sep 2020 20:39:45

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:06:05

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-12T15:36:34', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'f55d47ff-c4d1-446a-9f14-a2601b6249b2'	System	12 Sep 2020 20:37:04
User entered 'None (0)'	System	12 Sep 2020 20:37:04

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:06:05

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-12T15:36:40', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'f55d47ff-c4d1-446a-9f14-a2601b6249b2'	System	12 Sep 2020 20:37:04
User entered 'None (0)'	System	12 Sep 2020 20:37:04

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:06:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-12T15:36:43', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'f55d47ff-c4d1-446a-9f14-a2601b6249b2'	System	12 Sep 2020 20:37:04
User entered 'None (0)'	System	12 Sep 2020 20:37:04

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:06:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-12T15:36:46', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'f55d47ff-c4d1-446a-9f14-a2601b6249b2'	System	12 Sep 2020 20:37:04
User entered 'None (0)'	System	12 Sep 2020 20:37:04

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:06:05

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-12T15:36:49', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'f55d47ff-c4d1-446a-9f14-a2601b6249b2'	System	12 Sep 2020 20:37:04
User entered 'None (0)'	System	12 Sep 2020 20:37:04



US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:06:05

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-12T15:36:52', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'f55d47ff-c4d1-446a-9f14-a2601b6249b2'	System	12 Sep 2020 20:37:04
User entered 'None (0)'	System	12 Sep 2020 20:37:04

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:06:05

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)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-12T15:36:59', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'f55d47ff-c4d1-446a-9f14-a2601b6249b2'	System	12 Sep 2020 20:37:04
User entered 'No (N)'	System	12 Sep 2020 20:37:04

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:06:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-12T15:37:03', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'f55d47ff-c4d1-446a-9f14-a2601b6249b2'	System	12 Sep 2020 20:37:04
User entered '12 Sep 2020 15:37'	System	12 Sep 2020 20:37:04

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:06:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 20:39:45

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:06:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 20:39:45

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:06:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
Data entry locked.	System	11 Sep 2020 20:39:45
User entered 'Day 3'	System	11 Sep 2020 20:39:45

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:06:05

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-13T21:00:01', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '82a73142-3792-45e0-a731-e8c32f96d801'	System	14 Sep 2020 02:00:31
User entered 'None (0)'	System	14 Sep 2020 02:00:31

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:06:05

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-13T21:00:05', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '82a73142-3792-45e0-a731-e8c32f96d801'	System	14 Sep 2020 02:00:31
User entered 'None (0)'	System	14 Sep 2020 02:00:31



US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:06:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-13T21:00:08', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '82a73142-3792-45e0-a731-e8c32f96d801'	System	14 Sep 2020 02:00:31
User entered 'None (0)'	System	14 Sep 2020 02:00:31

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:06:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-13T21:00:12', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '82a73142-3792-45e0-a731-e8c32f96d801'	System	14 Sep 2020 02:00:31
User entered 'None (0)'	System	14 Sep 2020 02:00:31

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:06:05

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-13T21:00:16', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '82a73142-3792-45e0-a731-e8c32f96d801'	System	14 Sep 2020 02:00:31
User entered 'None (0)'	System	14 Sep 2020 02:00:31

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:06:05

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-13T21:00:18', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '82a73142-3792-45e0-a731-e8c32f96d801'	System	14 Sep 2020 02:00:31
User entered 'None (0)'	System	14 Sep 2020 02:00:31

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:06:05

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)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-13T21:00:23', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '82a73142-3792-45e0-a731-e8c32f96d801'	System	14 Sep 2020 02:00:31
User entered 'No (N)'	System	14 Sep 2020 02:00:31

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:06:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-13T21:00:28', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '82a73142-3792-45e0-a731-e8c32f96d801'	System	14 Sep 2020 02:00:31
User entered '13 Sep 2020 21:00'	System	14 Sep 2020 02:00:31

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:06:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 20:39:45

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:06:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 20:39:45



US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:06:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
Data entry locked.	System	11 Sep 2020 20:39:45
User entered 'Day 4'	System	11 Sep 2020 20:39:45

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:06:05

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-14T13:20:48', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'ed617d6c-e37c-40ed-9594-8cc6908f6ff5'	System	14 Sep 2020 18:21:13
User entered 'None (0)'	System	14 Sep 2020 18:21:13

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:06:05

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-14T13:20:51', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'ed617d6c-e37c-40ed-9594-8cc6908f6ff5'	System	14 Sep 2020 18:21:13
User entered 'None (0)'	System	14 Sep 2020 18:21:13

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:06:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-14T13:20:54', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'ed617d6c-e37c-40ed-9594-8cc6908f6ff5'	System	14 Sep 2020 18:21:13
User entered 'None (0)'	System	14 Sep 2020 18:21:13

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:06:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-14T13:20:57', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'ed617d6c-e37c-40ed-9594-8cc6908f6ff5'	System	14 Sep 2020 18:21:13
User entered 'None (0)'	System	14 Sep 2020 18:21:13

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:06:05

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-14T13:21:00', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'ed617d6c-e37c-40ed-9594-8cc6908f6ff5'	System	14 Sep 2020 18:21:13
User entered 'None (0)'	System	14 Sep 2020 18:21:13

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:06:05

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-14T13:21:02', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'ed617d6c-e37c-40ed-9594-8cc6908f6ff5'	System	14 Sep 2020 18:21:13
User entered 'None (0)'	System	14 Sep 2020 18:21:13

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:06:05

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)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-14T13:21:07', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'ed617d6c-e37c-40ed-9594-8cc6908f6ff5'	System	14 Sep 2020 18:21:13
User entered 'No (N)'	System	14 Sep 2020 18:21:13



US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:06:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-14T13:21:11', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'ed617d6c-e37c-40ed-9594-8cc6908f6ff5'	System	14 Sep 2020 18:21:13
User entered '14 Sep 2020 13:21'	System	14 Sep 2020 18:21:13

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:06:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 20:39:45

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:06:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 20:39:45

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:06:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
Data entry locked.	System	11 Sep 2020 20:39:45
User entered 'Day 5'	System	11 Sep 2020 20:39:45

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:06:05

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-15T12:09:54', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '05713fa5-2175-48f9-9242-7b85e869fb84'	System	15 Sep 2020 17:10:20
User entered 'None (0)'	System	15 Sep 2020 17:10:20

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:06:05

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-15T12:09:56', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '05713fa5-2175-48f9-9242-7b85e869fb84'	System	15 Sep 2020 17:10:20
User entered 'None (0)'	System	15 Sep 2020 17:10:20

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:06:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-15T12:09:59', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '05713fa5-2175-48f9-9242-7b85e869fb84'	System	15 Sep 2020 17:10:20
User entered 'None (0)'	System	15 Sep 2020 17:10:20

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:06:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-15T12:10:01', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '05713fa5-2175-48f9-9242-7b85e869fb84'	System	15 Sep 2020 17:10:20
User entered 'None (0)'	System	15 Sep 2020 17:10:20



US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:06:05

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-15T12:10:04', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '05713fa5-2175-48f9-9242-7b85e869fb84'	System	15 Sep 2020 17:10:20
User entered 'None (0)'	System	15 Sep 2020 17:10:20

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:06:05

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-15T12:10:06', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '05713fa5-2175-48f9-9242-7b85e869fb84'	System	15 Sep 2020 17:10:20
User entered 'None (0)'	System	15 Sep 2020 17:10:20

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:06:05

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)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-15T12:10:12', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '05713fa5-2175-48f9-9242-7b85e869fb84'	System	15 Sep 2020 17:10:20
User entered 'No (N)'	System	15 Sep 2020 17:10:20

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:06:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-15T12:10:15', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '05713fa5-2175-48f9-9242-7b85e869fb84'	System	15 Sep 2020 17:10:20
User entered '15 Sep 2020 12:10'	System	15 Sep 2020 17:10:20

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:06:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 20:39:45

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:06:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 20:39:45

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:06:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
Data entry locked.	System	11 Sep 2020 20:39:45
User entered 'Day 6'	System	11 Sep 2020 20:39:45

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:06:05

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-16T13:05:54', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '619625cc-c1d2-447d-b175-7fe153b098af'	System	16 Sep 2020 18:06:40
User entered 'None (0)'	System	16 Sep 2020 18:06:40



US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:06:05

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-16T13:06:07', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '619625cc-c1d2-447d-b175-7fe153b098af'	System	16 Sep 2020 18:06:40
User entered 'Some interference with activity (2)'	System	16 Sep 2020 18:06:40

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:06:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-16T13:06:13', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '619625cc-c1d2-447d-b175-7fe153b098af'	System	16 Sep 2020 18:06:40
User entered 'Some interference with activity (2)'	System	16 Sep 2020 18:06:40

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:06:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-16T13:06:18', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '619625cc-c1d2-447d-b175-7fe153b098af'	System	16 Sep 2020 18:06:40
User entered 'Some interference with activity (2)'	System	16 Sep 2020 18:06:40

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:06:05

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-16T13:06:22', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '619625cc-c1d2-447d-b175-7fe153b098af'	System	16 Sep 2020 18:06:40
User entered 'None (0)'	System	16 Sep 2020 18:06:40

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:06:05

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-16T13:06:27', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '619625cc-c1d2-447d-b175-7fe153b098af'	System	16 Sep 2020 18:06:40
User entered 'None (0)'	System	16 Sep 2020 18:06:40

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:06:05

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)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-16T13:06:31', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '619625cc-c1d2-447d-b175-7fe153b098af'	System	16 Sep 2020 18:06:40
User entered 'No (N)'	System	16 Sep 2020 18:06:40

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:06:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-16T13:06:33', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '619625cc-c1d2-447d-b175-7fe153b098af'	System	16 Sep 2020 18:06:40
User entered '16 Sep 2020 13:06'	System	16 Sep 2020 18:06:40

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:06:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 20:39:45



US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:06:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 20:39:45

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:06:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
Data entry locked.	System	11 Sep 2020 20:39:45
User entered 'Day 7'	System	11 Sep 2020 20:39:45

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:06:05

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-17T18:33:50', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '3cae2098-5c6a-4833-b27e-a659eac2b6e8'	System	17 Sep 2020 23:34:11
User entered 'None (0)'	System	17 Sep 2020 23:34:11

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:06:05

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-17T18:33:53', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '3cae2098-5c6a-4833-b27e-a659eac2b6e8'	System	17 Sep 2020 23:34:11
User entered 'None (0)'	System	17 Sep 2020 23:34:11

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:06:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-17T18:33:55', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '3cae2098-5c6a-4833-b27e-a659eac2b6e8'	System	17 Sep 2020 23:34:11
User entered 'None (0)'	System	17 Sep 2020 23:34:11

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:06:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-17T18:33:57', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '3cae2098-5c6a-4833-b27e-a659eac2b6e8'	System	17 Sep 2020 23:34:11
User entered 'None (0)'	System	17 Sep 2020 23:34:11

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:06:05

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-17T18:34:00', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '3cae2098-5c6a-4833-b27e-a659eac2b6e8'	System	17 Sep 2020 23:34:11
User entered 'None (0)'	System	17 Sep 2020 23:34:11

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:06:05

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-17T18:34:02', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '3cae2098-5c6a-4833-b27e-a659eac2b6e8'	System	17 Sep 2020 23:34:11
User entered 'None (0)'	System	17 Sep 2020 23:34:11



US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:06:05

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)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-17T18:34:06', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '3cae2098-5c6a-4833-b27e-a659eac2b6e8'	System	17 Sep 2020 23:34:11
User entered 'No (N)'	System	17 Sep 2020 23:34:11

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:06:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-09-17T18:34:09', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '3cae2098-5c6a-4833-b27e-a659eac2b6e8'	System	17 Sep 2020 23:34:11
User entered '17 Sep 2020 18:34'	System	17 Sep 2020 23:34:11

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:06:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 20:39:45

US3312637

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:06:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 20:39:45

**US3312637**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:06:05**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:58:32
User entered 'Yes (Y)'	Karol Moore (b) (4)	30 Sep 2020 23:20:44

US3312637

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:58:32
User entered '18 Sep 2020'	Karol Moore (b) (4)	30 Sep 2020 23:20:44

US3312637

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:58:32
User entered 'Contact Made (CONTACT MADE)'	Karol Moore (b) (4)	30 Sep 2020 23:20:44

US3312637

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:05

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:58:32
User entered empty.	Karol Moore (b) (4)	30 Sep 2020 23:20:44



US3312637

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:58:37
User entered 'Yes (Y)'	Karol Moore (b) (4)	30 Sep 2020 23:20:46

US3312637

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered 'I'	System	30 Sep 2020 23:20:46

**US3312637**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:06:05**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:59:07
User entered 'Yes (Y)'	Karol Moore (b) (4)	30 Sep 2020 23:21:10

US3312637

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:05

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:59:07
User entered '25 Sep 2020'	Karol Moore (b) (4)	30 Sep 2020 23:21:10

US3312637

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:59:07
User entered 'Contact Made (CONTACT MADE)'	Karol Moore (b) (4)	30 Sep 2020 23:21:10

US3312637

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:05

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:59:07
User entered empty.	Karol Moore (b) (4)	30 Sep 2020 23:21:10

US3312637

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:59:13
User entered 'Yes (Y)'	Karol Moore (b) (4)	30 Sep 2020 23:21:13

US3312637

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered 'I'	System	30 Sep 2020 23:21:13



**US3312637**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:06:05**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:00:31
User entered 'Yes (Y)'	Karol Moore (b) (4)	05 Oct 2020 17:24:06

US3312637

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:05

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:00:31
User entered '02 Oct 2020'	Karol Moore (b) (4)	05 Oct 2020 17:24:06

US3312637

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:00:31
User entered 'Contact Made (CONTACT MADE)'	Karol Moore (b) (4)	05 Oct 2020 17:24:06

US3312637

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:05

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:00:31
User entered empty.	Karol Moore (b) (4)	05 Oct 2020 17:24:06

US3312637

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:00:36
User entered 'Yes (Y)'	Karol Moore (b) (4)	05 Oct 2020 17:23:50

US3312637

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:47:04
User entered 'I'	System	05 Oct 2020 17:23:50

US3312637

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:01:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 20:02:54

US3312637

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:05

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:01:35
User entered '09 Oct 2020'	(b) (4), (b) (6)	20 Oct 2020 20:02:54



US3312637

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:05

[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 19:01:28
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:01:35
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	20 Oct 2020 20:02:54

**US3312637**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:06:05**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User entered 'VISIT2'	System	20 Oct 2020 20:02:54

US3312637

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	20 Oct 2020 20:03:41

US3312637

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:02:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 20:03:41

US3312637

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:02:14
User entered '09 Oct 2020'	(b) (4), (b) (6)	20 Oct 2020 20:03:41

**US3312637**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:06:05**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:02:14
User entered '10:40'	(b) (4), (b) (6)	20 Oct 2020 20:03:41

US3312637

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User entered '09 Oct 2020 10:40'	System	20 Oct 2020 20:03:41

US3312637

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:02:14
User entered '98.0' F	(b) (4), (b) (6)	20 Oct 2020 20:03:41



US3312637

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:02:14
User entered 'Oral (Oral)'	(b) (4), (b) (6)	20 Oct 2020 20:03:41

US3312637

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:02:14
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 20:03:41

US3312637

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:02:14
User entered '78'	(b) (4), (b) (6)	20 Oct 2020 20:03:41

US3312637

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User entered 'bpm'	System	20 Oct 2020 20:03:41

US3312637

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:02:14
User entered '14'	(b) (4), (b) (6)	20 Oct 2020 20:03:41

US3312637

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User entered 'breaths/min'	System	20 Oct 2020 20:03:41

US3312637

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:02:14
User entered '140'	(b) (4), (b) (6)	20 Oct 2020 20:03:41

US3312637

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User entered 'mmHg'	System	20 Oct 2020 20:03:41



US3312637

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:02:14
User entered '66'	(b) (4), (b) (6)	20 Oct 2020 20:03:41

US3312637

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User entered 'mmHg'	System	20 Oct 2020 20:03:41

US3312637

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	20 Oct 2020 20:03:41

US3312637

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:02:14
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 20:03:41

US3312637

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:02:14
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 20:03:41

US3312637

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:02:14
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 20:03:41

US3312637

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User entered empty.	System	20 Oct 2020 20:03:41

US3312637

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:02:14
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 20:03:41



US3312637

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:02:14
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 20:03:41

US3312637

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:02:14
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 20:03:41

US3312637

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:02:14
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 20:03:41

US3312637

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User entered empty.	System	20 Oct 2020 20:03:41

US3312637

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:02:14
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 20:03:41

US3312637

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User entered empty.	System	20 Oct 2020 20:03:41

US3312637

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:02:14
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 20:03:41

US3312637

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User entered empty.	System	20 Oct 2020 20:03:41



US3312637

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:02:14
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 20:03:41

US3312637

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User entered empty.	System	20 Oct 2020 20:03:41

US3312637

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:06:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:02:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 20:03:50

US3312637

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:06:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:02:24
User entered '09 Oct 2020'	(b) (4), (b) (6)	20 Oct 2020 20:03:50

US3312637

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:05

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:03:47
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 20:09:55

US3312637

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:05

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:03:47
User entered 'Physician Decision (PHYSICIAN DECISION)'	(b) (4), (b) (6)	20 Oct 2020 20:09:55

US3312637

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:05

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 19:01:28
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:03:47
User entered 'IP initially withheld with possible dosing at a later date, But due to SAE development (stent placement not known initially). IP withheld for subject safety'	(b) (4), (b) (6)	20 Oct 2020 20:09:55

US3312637

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:05

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User entered empty.	System	20 Oct 2020 20:09:55



US3312637

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:05

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:03:47
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 20:09:55

US3312637

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:05

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:03:47
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 20:09:55

US3312637

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:05

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User entered empty.	System	20 Oct 2020 20:09:55

US3312637

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:05

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:03:47
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 20:09:55

US3312637

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:05

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:03:47
User entered empty.	System	20 Oct 2020 20:09:55

US3312637

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:05

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User entered empty.	System	20 Oct 2020 20:09:55

US3312637

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:03:54
User entered 'No (N)'	Karol Moore (b) (4)	02 Nov 2020 16:02:05

US3312637

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:05

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:03:54
User entered empty.	Karol Moore (b) (4)	02 Nov 2020 16:02:05



**US3312637**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:06:05**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:03:54
User entered empty.	Karol Moore (b) (4)	02 Nov 2020 16:02:05

US3312637

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:05

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User entered empty.	System	02 Nov 2020 16:02:05

US3312637

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:06:05

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:36:01
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
User entered empty.	Karol Moore (b) (4)	26 Feb 2021 20:54:10

US3312637

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:06:05

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Karol Moore (b) (4)	26 Feb 2021 20:54:10

US3312637

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:06:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:36:01
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
User entered 'No (N)'	Karol Moore (b) (4)	26 Feb 2021 20:54:10

**US3312637**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:06:05**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:36:01
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
User entered empty.	Karol Moore (b) (4)	26 Feb 2021 20:54:10

**US3312637**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:06:05**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User entered empty.	System	26 Feb 2021 20:54:10

US3312637

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:06:05

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Karol Moore (b) (4)	26 Feb 2021 20:54:10



US3312637

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:06:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:36:01
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
User entered 'No (N)'	Karol Moore (b) (4)	26 Feb 2021 20:54:10

**US3312637**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:06:05**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:36:01
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
User entered empty.	Karol Moore (b) (4)	26 Feb 2021 20:54:10

US3312637

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:06:05

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User entered empty.	System	26 Feb 2021 20:54:10

US3312637

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:04:04
User entered 'Yes (Y)'	Karol Moore (b) (4)	02 Nov 2020 16:02:24

US3312637

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User entered '1'	System	02 Nov 2020 16:02:24

US3312637

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:17:50
User entered 'Yes (Y)'	Karol Moore (b) (4)	02 Nov 2020 16:02:53

US3312637

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:17:50
User entered '19 Oct 2020'	Karol Moore (b) (4)	02 Nov 2020 16:02:53

US3312637

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:17:50
User entered 'Contact Made (CONTACT MADE)'	Karol Moore (b) (4)	02 Nov 2020 16:02:53



US3312637

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:05

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:17:50
User entered empty.	Karol Moore (b) (4)	02 Nov 2020 16:02:53

US3312637

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:17:55
User entered 'Yes (Y)'	Karol Moore (b) (4)	02 Nov 2020 16:03:01

US3312637

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User entered 'I'	System	02 Nov 2020 16:03:01

**US3312637**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:06:05**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:18:08
User entered 'Yes (Y)'	Karol Moore (b) (4)	02 Nov 2020 16:03:22

**US3312637**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:06:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:18:08
User entered '23 Oct 2020'	Karol Moore (b) (4)	02 Nov 2020 16:03:22

US3312637

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:18:08
User entered 'Contact Made (CONTACT MADE)'	Karol Moore (b) (4)	02 Nov 2020 16:03:22

US3312637

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:05

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:18:08
User entered empty.	Karol Moore (b) (4)	02 Nov 2020 16:03:22

US3312637

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:18:17
User entered 'Yes (Y)'	Karol Moore (b) (4)	02 Nov 2020 16:03:28



**US3312637**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:06:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User entered 'I'	System	02 Nov 2020 16:03:28

**US3312637**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:06:05**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:19:30
User entered 'Yes (Y)'	Karol Moore (b) (4)	02 Nov 2020 16:03:46

US3312637

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:19:30
User entered '30 Oct 2020'	Karol Moore (b) (4)	02 Nov 2020 16:03:46

US3312637

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:19:30
User entered 'Contact Made (CONTACT MADE)'	Karol Moore (b) (4)	02 Nov 2020 16:03:46

US3312637

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:05

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:19:30
User entered empty.	Karol Moore (b) (4)	02 Nov 2020 16:03:46

US3312637

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:19:39
User entered 'Yes (Y)'	Karol Moore (b) (4)	02 Nov 2020 16:06:00

US3312637

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User entered 'I'	System	02 Nov 2020 16:06:00

**US3312637**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:06:05**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:20:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Nov 2020 18:52:00



**US3312637**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:06:05**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:20:34
User entered '06 Nov 2020'	(b) (4), (b) (6)	06 Nov 2020 18:52:00

US3312637

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:05

[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 19:01:28
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:20:34
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	06 Nov 2020 18:52:00

**US3312637**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:06:05**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User entered 'VISIT3'	System	06 Nov 2020 18:52:00

US3312637

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:21:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Nov 2020 18:52:24

US3312637

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:21:32
User entered '06 Nov 2020'	(b) (4), (b) (6)	06 Nov 2020 18:52:24

US3312637

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:21:32
User entered '10:17'	(b) (4), (b) (6)	06 Nov 2020 18:52:24

US3312637

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User entered '06 Nov 2020 10:17'	System	06 Nov 2020 18:52:24

US3312637

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:21:32
User entered '98.7' F	(b) (4), (b) (6)	06 Nov 2020 18:52:24



US3312637

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:21:32
User entered 'Oral (Oral)'	(b) (4), (b) (6)	06 Nov 2020 18:52:24

US3312637

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:21:32
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 18:52:24

US3312637

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:21:32
User entered '83'	(b) (4), (b) (6)	06 Nov 2020 18:52:24

US3312637

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User entered 'bpm'	System	06 Nov 2020 18:52:24

US3312637

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:21:32
User entered '16'	(b) (4), (b) (6)	06 Nov 2020 18:52:24

US3312637

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User entered 'breaths/min'	System	06 Nov 2020 18:52:24

US3312637

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:21:32
User entered '132'	(b) (4), (b) (6)	06 Nov 2020 18:52:24

US3312637

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User entered 'mmHg'	System	06 Nov 2020 18:52:24



**US3312637**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:06:05**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:21:32
User entered '83'	(b) (4), (b) (6)	06 Nov 2020 18:52:24

US3312637

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User entered 'mmHg'	System	06 Nov 2020 18:52:24

US3312637

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:05

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28

US3312637

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:05

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28

US3312637

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:06:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:21:46
User entered 'Yes (Y)' reason for change: Data Entry Error		06 Nov 2020 18:52:58
User entered 'No (N)'		06 Nov 2020 18:52:28

US3312637

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:06:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:21:46
User entered '06 Nov 2020' reason for change: Data Entry Error		06 Nov 2020 18:52:58
User entered empty.		06 Nov 2020 18:52:28

US3312637

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:22:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Nov 2020 18:52:45

US3312637

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:05

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:22:01
User entered '06 Nov 2020'	(b) (4), (b) (6)	06 Nov 2020 18:52:45



US3312637

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:05

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:22:01
User entered '10:29'	(b) (4), (b) (6)	06 Nov 2020 18:52:45

US3312637

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User entered '06 Nov 2020 10:29'	System	06 Nov 2020 18:52:45

US3312637

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:22:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Nov 2020 18:51:48

**US3312637**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:06:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User entered 'I'	System	06 Nov 2020 18:51:48

US3312637

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
Data entry locked.	System	11 Sep 2020 20:39:45
User entered 'Day 64'	System	11 Sep 2020 20:39:45

US3312637

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

[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)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-11-11T12:13:39', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'e591c728-981d-41e4-89d1-1ff16de01e51'	System	11 Nov 2020 18:14:07
User entered 'No (N)'	System	11 Nov 2020 18:14:07

US3312637

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

Have you been exposed to someone with 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)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-11-11T12:13:45', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'e591c728-981d-41e4-89d1-1ff16de01e51'	System	11 Nov 2020 18:14:07
User entered 'No (N)'	System	11 Nov 2020 18:14:07

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-11-11T12:14:02', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'e591c728-981d-41e4-89d1-1ff16de01e51'	System	11 Nov 2020 18:14:07
User entered '11 Nov 2020 12:14:02'	System	11 Nov 2020 18:14:07



**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
Data entry locked.	System	11 Sep 2020 20:39:45
User entered '11 Nov 2020 00:01'	System	11 Sep 2020 20:39:45

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
Data entry locked.	System	11 Sep 2020 20:39:45
User entered '15 Nov 2020 23:59'	System	11 Sep 2020 20:39:45

US3312637

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
Data entry locked.	System	11 Sep 2020 20:39:45
User entered 'Day 71'	System	11 Sep 2020 20:39:45

US3312637

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

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)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-11-18T17:20:07', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '1688f7b9-fcd8-40c5-941b-1788f419e9c7'	System	18 Nov 2020 23:20:20
User entered 'No (N)'	System	18 Nov 2020 23:20:20

US3312637

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:05

Have you been exposed to someone with 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)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-11-18T17:20:12', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '1688f7b9-fcd8-40c5-941b-1788f419e9c7'	System	18 Nov 2020 23:20:20
User entered 'No (N)'	System	18 Nov 2020 23:20:20

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-11-18T17:20:17', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '1688f7b9-fcd8-40c5-941b-1788f419e9c7'	System	18 Nov 2020 23:20:20
User entered '18 Nov 2020 17:20:17'	System	18 Nov 2020 23:20:20

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
Data entry locked.	System	11 Sep 2020 20:39:45
User entered '18 Nov 2020 00:01'	System	11 Sep 2020 20:39:45

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:31:52
Data entry locked.	System	11 Sep 2020 20:39:45
User entered '22 Nov 2020 23:59'	System	11 Sep 2020 20:39:45



**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[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 (a5603d8e79580c11)', Time: '2020-11-22T00:48:26', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'f18c51f5-107a-4d17-be57-7586b39a9fe0'	System	22 Nov 2020 06:49:00
User entered 'No (N)'	System	22 Nov 2020 06:49:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Have you been exposed to someone with 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 (a5603d8e79580c11)', Time: '2020-11-22T00:48:49', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'f18c51f5-107a-4d17-be57-7586b39a9fe0'	System	22 Nov 2020 06:49:00
User entered 'No (N)'	System	22 Nov 2020 06:49:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-11-22T00:48:56', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'f18c51f5-107a-4d17-be57-7586b39a9fe0'	System	22 Nov 2020 06:49:00
User entered '22 Nov 2020 00:48:56'	System	22 Nov 2020 06:49:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[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 (a5603d8e79580c11)', Time: '2020-11-29T00:02:10', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'c3db2461-a137-4edd-ab03-06031431844a'	System	29 Nov 2020 06:02:26
User entered 'No (N)'	System	29 Nov 2020 06:02:26



**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Have you been exposed to someone with 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 (a5603d8e79580c11)', Time: '2020-11-29T00:02:18', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'c3db2461-a137-4edd-ab03-06031431844a'	System	29 Nov 2020 06:02:26
User entered 'No (N)'	System	29 Nov 2020 06:02:26

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-11-29T00:02:21', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'c3db2461-a137-4edd-ab03-06031431844a'	System	29 Nov 2020 06:02:26
User entered '29 Nov 2020 00:02:21'	System	29 Nov 2020 06:02:26

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[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 (a5603d8e79580c11)', Time: '2020-12-06T07:42:17', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'fba42e81-ab0d-4547-8449-1cc2204fd51e'	System	06 Dec 2020 13:42:35
User entered 'No (N)'	System	06 Dec 2020 13:42:35

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

Have you been exposed to someone with 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 (a5603d8e79580c11)', Time: '2020-12-06T07:42:23', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'fba42e81-ab0d-4547-8449-1cc2204fd51e'	System	06 Dec 2020 13:42:35
User entered 'No (N)'	System	06 Dec 2020 13:42:35

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-12-06T07:42:30', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'fba42e81-ab0d-4547-8449-1cc2204fd51e'	System	06 Dec 2020 13:42:35
User entered '06 Dec 2020 07:42:30'	System	06 Dec 2020 13:42:35



**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[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 (a5603d8e79580c11)', Time: '2020-12-13T08:34:45', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'd31bde79-7174-4a23-ba82-7d51fc269259'	System	13 Dec 2020 14:35:29
User entered 'No (N)'	System	13 Dec 2020 14:35:29

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

Have you been exposed to someone with 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 (a5603d8e79580c11)', Time: '2020-12-13T08:34:52', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'd31bde79-7174-4a23-ba82-7d51fc269259'	System	13 Dec 2020 14:35:29
User entered 'Yes (Y)'	System	13 Dec 2020 14:35:29

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Please 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 (a5603d8e79580c11)', Time: '2020-12-13T08:35:01', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'd31bde79-7174-4a23-ba82-7d51fc269259'	System	13 Dec 2020 14:35:29
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	13 Dec 2020 14:35:29

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-12-13T08:35:06', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'd31bde79-7174-4a23-ba82-7d51fc269259'	System	13 Dec 2020 14:35:29
User entered '13 Dec 2020 08:35:06'	System	13 Dec 2020 14:35:29

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 07:50:00



**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[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 (a5603d8e79580c11)', Time: '2020-12-20T00:33:51', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '377e8ecf-6680-411f-8599-c0f3442f8a89'	System	20 Dec 2020 06:34:03
User entered 'No (N)'	System	20 Dec 2020 06:34:03

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Have you been exposed to someone with 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 (a5603d8e79580c11)', Time: '2020-12-20T00:33:59', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '377e8ecf-6680-411f-8599-c0f3442f8a89'	System	20 Dec 2020 06:34:03
User entered 'No (N)'	System	20 Dec 2020 06:34:03

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-12-20T00:34:05', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '377e8ecf-6680-411f-8599-c0f3442f8a89'	System	20 Dec 2020 06:34:03
User entered '20 Dec 2020 00:34:05'	System	20 Dec 2020 06:34:03

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 07:50:00



**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[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 (a5603d8e79580c11)', Time: '2020-12-27T00:34:38', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '5b0a73a7-c575-403f-938b-94ba1d9e3379'	System	27 Dec 2020 06:34:54
User entered 'No (N)'	System	27 Dec 2020 06:34:54

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

Have you been exposed to someone with 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 (a5603d8e79580c11)', Time: '2020-12-27T00:34:46', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '5b0a73a7-c575-403f-938b-94ba1d9e3379'	System	27 Dec 2020 06:34:54
User entered 'No (N)'	System	27 Dec 2020 06:34:54

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2020-12-27T00:34:51', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '5b0a73a7-c575-403f-938b-94ba1d9e3379'	System	27 Dec 2020 06:34:54
User entered '27 Dec 2020 00:34:51'	System	27 Dec 2020 06:34:54

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[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 (a5603d8e79580c11)', Time: '2021-01-03T14:40:36', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'bff0fe0f-87ac-481f-99f1-a1085f9f0b51'	System	03 Jan 2021 20:41:00
User entered 'No (N)'	System	03 Jan 2021 20:41:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

Have you been exposed to someone with 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 (a5603d8e79580c11)', Time: '2021-01-03T14:40:41', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'bff0fe0f-87ac-481f-99f1-a1085f9f0b51'	System	03 Jan 2021 20:41:00
User entered 'No (N)'	System	03 Jan 2021 20:41:00



**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2021-01-03T14:40:55', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'bff0fe0f-87ac-481f-99f1-a1085f9f0b51'	System	03 Jan 2021 20:41:00
User entered '03 Jan 2021 14:40:55'	System	03 Jan 2021 20:41:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[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 (a5603d8e79580c11)', Time: '2021-01-10T00:02:35', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '3b35d5dd-a666-4d35-8081-9b5627dd197f'	System	10 Jan 2021 06:02:48
User entered 'No (N)'	System	10 Jan 2021 06:02:48

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Have you been exposed to someone with 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 (a5603d8e79580c11)', Time: '2021-01-10T00:02:39', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '3b35d5dd-a666-4d35-8081-9b5627dd197f'	System	10 Jan 2021 06:02:48
User entered 'No (N)'	System	10 Jan 2021 06:02:48

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2021-01-10T00:02:43', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '3b35d5dd-a666-4d35-8081-9b5627dd197f' User entered '10 Jan 2021 00:02:43'	System	10 Jan 2021 06:02:48

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 07:50:00



**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[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 (a5603d8e79580c11)', Time: '2021-01-17T00:03:20', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '1692da4f-d8ff-40f2-aca0-3b176a5ae9c5'	System	17 Jan 2021 06:03:29
User entered 'No (N)'	System	17 Jan 2021 06:03:29

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

Have you been exposed to someone with 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 (a5603d8e79580c11)', Time: '2021-01-17T00:03:23', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '1692da4f-d8ff-40f2-aca0-3b176a5ae9c5'	System	17 Jan 2021 06:03:29
User entered 'No (N)'	System	17 Jan 2021 06:03:29

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2021-01-17T00:03:26', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '1692da4f-d8ff-40f2-aca0-3b176a5ae9c5'	System	17 Jan 2021 06:03:29
User entered '17 Jan 2021 00:03:26'	System	17 Jan 2021 06:03:29

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 07:50:00



**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[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 (a5603d8e79580c11)', Time: '2021-01-24T00:36:07', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'f1f59ef0-cb2f-4a2f-89f2-4acbcafb9a74'	System	24 Jan 2021 06:36:20
User entered 'No (N)'	System	24 Jan 2021 06:36:20

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

Have you been exposed to someone with 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 (a5603d8e79580c11)', Time: '2021-01-24T00:36:11', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'f1f59ef0-cb2f-4a2f-89f2-4acbcafb9a74'	System	24 Jan 2021 06:36:20
User entered 'No (N)'	System	24 Jan 2021 06:36:20

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2021-01-24T00:36:15', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'f1f59ef0-cb2f-4a2f-89f2-4acbcafb9a74'	System	24 Jan 2021 06:36:20
User entered '24 Jan 2021 00:36:15'	System	24 Jan 2021 06:36:20

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[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 (a5603d8e79580c11)', Time: '2021-01-31T00:02:20', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '2040d361-3513-4bfe-89a6-384f076c4e06'	System	31 Jan 2021 06:02:52
User entered 'No (N)'	System	31 Jan 2021 06:02:52

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

Have you been exposed to someone with 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 (a5603d8e79580c11)', Time: '2021-01-31T00:02:23', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '2040d361-3513-4bfe-89a6-384f076c4e06'	System	31 Jan 2021 06:02:52
User entered 'No (N)'	System	31 Jan 2021 06:02:52



**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2021-01-31T00:02:28', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '2040d361-3513-4bfe-89a6-384f076c4e06'	System	31 Jan 2021 06:02:52
User entered '31 Jan 2021 00:02:28'	System	31 Jan 2021 06:02:52

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[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 (a5603d8e79580c11)', Time: '2021-02-08T00:21:19', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '0bd20023-df07-456d-ac11-3d0f74a3f4e4'	System	08 Feb 2021 06:21:29
User entered 'No (N)'	System	08 Feb 2021 06:21:29

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

Have you been exposed to someone with 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 (a5603d8e79580c11)', Time: '2021-02-08T00:21:22', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '0bd20023-df07-456d-ac11-3d0f74a3f4e4'	System	08 Feb 2021 06:21:29
User entered 'No (N)'	System	08 Feb 2021 06:21:29

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2021-02-08T00:21:27', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '0bd20023-df07-456d-ac11-3d0f74a3f4e4'	System	08 Feb 2021 06:21:29
User entered '08 Feb 2021 00:21:27'	System	08 Feb 2021 06:21:29

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 07:50:00



**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[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 (a5603d8e79580c11)', Time: '2021-02-14T12:00:05', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '6f46e5dc-077d-4ab4-8980-3528286e7a5b'	System	14 Feb 2021 18:00:25
User entered 'No (N)'	System	14 Feb 2021 18:00:25

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

Have you been exposed to someone with 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 (a5603d8e79580c11)', Time: '2021-02-14T12:00:09', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '6f46e5dc-077d-4ab4-8980-3528286e7a5b'	System	14 Feb 2021 18:00:25
User entered 'No (N)'	System	14 Feb 2021 18:00:25

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2021-02-14T12:00:13', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '6f46e5dc-077d-4ab4-8980-3528286e7a5b' User entered '14 Feb 2021 12:00:13'	System	14 Feb 2021 18:00:25

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 07:50:00



**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[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 (a5603d8e79580c11)', Time: '2021-02-21T21:26:49', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'da20f9ad-e38c-4df6-a386-c4d24d3bbabb'	System	22 Feb 2021 03:26:58
User entered 'No (N)'	System	22 Feb 2021 03:26:58

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

Have you been exposed to someone with 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 (a5603d8e79580c11)', Time: '2021-02-21T21:26:53', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'da20f9ad-e38c-4df6-a386-c4d24d3bbabb'	System	22 Feb 2021 03:26:58
User entered 'No (N)'	System	22 Feb 2021 03:26:58

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2021-02-21T21:26:56', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'da20f9ad-e38c-4df6-a386-c4d24d3bbabb'	System	22 Feb 2021 03:26:58
User entered '21 Feb 2021 21:26:56'	System	22 Feb 2021 03:26:58

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[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 (a5603d8e79580c11)', Time: '2021-02-28T00:26:42', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '445a6666-7866-4b97-a44e-71dbb1c995de'	System	28 Feb 2021 06:26:54
User entered 'No (N)'	System	28 Feb 2021 06:26:54

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

Have you been exposed to someone with 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 (a5603d8e79580c11)', Time: '2021-02-28T00:26:47', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '445a6666-7866-4b97-a44e-71dbb1c995de'	System	28 Feb 2021 06:26:54
User entered 'No (N)'	System	28 Feb 2021 06:26:54



**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2021-02-28T00:26:51', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '445a6666-7866-4b97-a44e-71dbb1c995de'	System	28 Feb 2021 06:26:54
User entered '28 Feb 2021 00:26:51'	System	28 Feb 2021 06:26:54

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[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 (a5603d8e79580c11)', Time: '2021-03-07T00:59:56', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '745f2853-bd31-49af-b245-006ad71519fd'	System	07 Mar 2021 07:00:10
User entered 'No (N)'	System	07 Mar 2021 07:00:10

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

Have you been exposed to someone with 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 (a5603d8e79580c11)', Time: '2021-03-07T01:00:03', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '745f2853-bd31-49af-b245-006ad71519fd'	System	07 Mar 2021 07:00:10
User entered 'No (N)'	System	07 Mar 2021 07:00:10

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2021-03-07T01:00:07', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '745f2853-bd31-49af-b245-006ad71519fd'	System	07 Mar 2021 07:00:10
User entered '07 Mar 2021 01:00:07'	System	07 Mar 2021 07:00:10

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 07:50:00



**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[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 (a5603d8e79580c11)', Time: '2021-03-14T05:24:45', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'fec325f5-9216-4e0a-ba17-2cadae69024a'	System	14 Mar 2021 10:25:06
User entered 'No (N)'	System	14 Mar 2021 10:25:06

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Have you been exposed to someone with 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 (a5603d8e79580c11)', Time: '2021-03-14T05:24:52', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'fec325f5-9216-4e0a-ba17-2cadae69024a'	System	14 Mar 2021 10:25:06
User entered 'No (N)'	System	14 Mar 2021 10:25:06

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2021-03-14T05:25:02', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'fec325f5-9216-4e0a-ba17-2cadae69024a'	System	14 Mar 2021 10:25:06
User entered '14 Mar 2021 05:25:02'	System	14 Mar 2021 10:25:06

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 07:50:00



**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[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 (a5603d8e79580c11)', Time: '2021-03-21T00:54:42', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '5639aa0a-01a2-4f18-94e9-2e6a18f32e98'	System	21 Mar 2021 05:54:57
User entered 'No (N)'	System	21 Mar 2021 05:54:57

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Have you been exposed to someone with 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 (a5603d8e79580c11)', Time: '2021-03-21T00:54:47', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '5639aa0a-01a2-4f18-94e9-2e6a18f32e98'	System	21 Mar 2021 05:54:57
User entered 'No (N)'	System	21 Mar 2021 05:54:57

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2021-03-21T00:54:54', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '5639aa0a-01a2-4f18-94e9-2e6a18f32e98' User entered '21 Mar 2021 00:54:54'	System	21 Mar 2021 05:54:57

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[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 (a5603d8e79580c11)', Time: '2021-03-28T13:30:49', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'bca4c790-a01c-40a6-af51-cdc638220838'	System	28 Mar 2021 18:30:57
User entered 'No (N)'	System	28 Mar 2021 18:30:57

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

Have you been exposed to someone with 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 (a5603d8e79580c11)', Time: '2021-03-28T13:30:51', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'bca4c790-a01c-40a6-af51-cdc638220838'	System	28 Mar 2021 18:30:57
User entered 'No (N)'	System	28 Mar 2021 18:30:57



**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2021-03-28T13:30:53', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'bca4c790-a01c-40a6-af51-cdc638220838' User entered '28 Mar 2021 13:30:53'	System	28 Mar 2021 18:30:57

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[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 (a5603d8e79580c11)', Time: '2021-04-04T11:37:40', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '17d41b01-0869-444b-9be9-9b6eacdfae09'	System	04 Apr 2021 16:38:03
User entered 'No (N)'	System	04 Apr 2021 16:38:03

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Have you been exposed to someone with 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 (a5603d8e79580c11)', Time: '2021-04-04T11:37:57', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '17d41b01-0869-444b-9be9-9b6eacdfae09'	System	04 Apr 2021 16:38:03
User entered 'No (N)'	System	04 Apr 2021 16:38:03

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2021-04-04T11:37:59', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '17d41b01-0869-444b-9be9-9b6eacdfae09'	System	04 Apr 2021 16:38:03
User entered '04 Apr 2021 11:37:59'	System	04 Apr 2021 16:38:03

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 07:50:00



**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[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 (a5603d8e79580c11)', Time: '2021-04-11T00:02:52', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'ee1ded7b-1e92-43d2-b387-16beda01e62c'	System	11 Apr 2021 05:03:05
User entered 'No (N)'	System	11 Apr 2021 05:03:05

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

Have you been exposed to someone with 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 (a5603d8e79580c11)', Time: '2021-04-11T00:02:55', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'ee1ded7b-1e92-43d2-b387-16beda01e62c'	System	11 Apr 2021 05:03:05
User entered 'No (N)'	System	11 Apr 2021 05:03:05

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2021-04-11T00:02:58', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'ee1ded7b-1e92-43d2-b387-16beda01e62c'	System	11 Apr 2021 05:03:05
User entered '11 Apr 2021 00:02:58'	System	11 Apr 2021 05:03:05

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 07:50:00



**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[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 (a5603d8e79580c11)', Time: '2021-04-18T01:35:50', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'b44106f7-ef4b-4a53-9499-9241e559be98'	System	18 Apr 2021 06:36:05
User entered 'No (N)'	System	18 Apr 2021 06:36:05

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

Have you been exposed to someone with 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 (a5603d8e79580c11)', Time: '2021-04-18T01:35:58', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'b44106f7-ef4b-4a53-9499-9241e559be98'	System	18 Apr 2021 06:36:05
User entered 'No (N)'	System	18 Apr 2021 06:36:05

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2021-04-18T01:36:04', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'b44106f7-ef4b-4a53-9499-9241e559be98'	System	18 Apr 2021 06:36:05
User entered '18 Apr 2021 01:36:04'	System	18 Apr 2021 06:36:05

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[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 (a5603d8e79580c11)', Time: '2021-04-25T13:36:04', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'd5100104-5ef5-430e-8e49-2e31c139fc77'	System	25 Apr 2021 18:36:12
User entered 'No (N)'	System	25 Apr 2021 18:36:12

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

Have you been exposed to someone with 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 (a5603d8e79580c11)', Time: '2021-04-25T13:36:07', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'd5100104-5ef5-430e-8e49-2e31c139fc77'	System	25 Apr 2021 18:36:12
User entered 'No (N)'	System	25 Apr 2021 18:36:12



**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2021-04-25T13:36:09', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: 'd5100104-5ef5-430e-8e49-2e31c139fc77'	System	25 Apr 2021 18:36:12
User entered '25 Apr 2021 13:36:09'	System	25 Apr 2021 18:36:12

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[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 (a5603d8e79580c11)', Time: '2021-05-02T01:56:05', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '9bd94c6f-03da-400d-9f60-39b34b94b0ec'	System	02 May 2021 06:56:20
User entered 'No (N)'	System	02 May 2021 06:56:20

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

Have you been exposed to someone with 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 (a5603d8e79580c11)', Time: '2021-05-02T01:56:10', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '9bd94c6f-03da-400d-9f60-39b34b94b0ec'	System	02 May 2021 06:56:20
User entered 'No (N)'	System	02 May 2021 06:56:20

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2021-05-02T01:56:15', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '9bd94c6f-03da-400d-9f60-39b34b94b0ec'	System	02 May 2021 06:56:20
User entered '02 May 2021 01:56:15'	System	02 May 2021 06:56:20

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 07:50:00



**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 07:50:00



**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 07:50:00



**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 07:50:00



**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 07:50:00



**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 07:50:00



**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 07:50:00



**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 07:50:00



**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 07:50:00



**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 07:50:00



**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 07:50:00



**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 07:50:00



**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 07:50:00



**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 07:50:00



**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 07:50:00



**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 07:50:00



**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 07:50:00



**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 07:50:00



**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 07:50:00



**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 07:50:00

**US3312637**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 07:50:00



**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 07:50:00



**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 07:50:00



**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 07:50:00



**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 07:50:00



**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 07:50:00



**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 07:50:00



**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 07:50:00



**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 07:50:00



**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 07:50:00



**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 07:50:00



**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '30 Oct 2022 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '03 Nov 2022 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '06 Nov 2022 00:01'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '10 Nov 2022 23:59'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 07:50:00

**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '13 Nov 2022 00:01'	System	20 Nov 2020 07:50:00



**US3312637**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:50:00
Amendment Manager: User entered '17 Nov 2022 23:59'	System	20 Nov 2020 07:50:00

US3312637

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 17:06:05**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2021-02-27T17:50:45', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '9757b56d-45d0-4a7e-b5ca-11d3c6b58837'	System	27 Feb 2021 23:50:53
User entered 'No (N)'	System	27 Feb 2021 23:50:53

**US3312637**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 17:06:05**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5603d8e79580c11)', Time: '2021-02-27T17:50:50', User OID: 'PatientReportedOutcome (US3312637)', ODM File OID: '9757b56d-45d0-4a7e-b5ca-11d3c6b58837'	System	27 Feb 2021 23:50:53
User entered '27 Feb 2021 17:50:50'	System	27 Feb 2021 23:50:53

**US3312637**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:06:05**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:22:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Dec 2020 18:24:05

**US3312637**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:06:05**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:22:41
User entered '04 Dec 2020'	(b) (4), (b) (6)	04 Dec 2020 18:24:05

**US3312637**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:06:05**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:22:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	04 Dec 2020 18:24:05

US3312637

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:05

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:22:41
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 18:24:05

**US3312637**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:06:05**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:23:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Dec 2020 18:24:09



US3312637

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:28
User entered 'I'	System	04 Dec 2020 18:24:09

US3312637

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:53:52
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 15:14:21
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Jan 2021 21:05:39

US3312637

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:05

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:53:52
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 15:14:21
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '06 Jan 2021'	(b) (4), (b) (6)	06 Jan 2021 21:05:39

US3312637

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:53:52
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 15:14:21
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	06 Jan 2021 21:05:39

US3312637

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:05

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:53:52
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 15:14:21
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered empty.	(b) (4), (b) (6)	06 Jan 2021 21:05:39

US3312637

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:53:52
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 15:14:27
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Jan 2021 21:05:56

US3312637

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:53:52
User entered 'I'	System	06 Jan 2021 21:05:56

US3312637

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:53:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:49:08
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Yes (Y)'	Karol Moore (b) (4)	08 Feb 2021 19:46:46



US3312637

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:05

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:53:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:49:08
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '04 Feb 2021'	Karol Moore (b) (4)	08 Feb 2021 19:46:46

US3312637

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:53:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:49:08
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Contact Made (CONTACT MADE)'	Karol Moore (b) (4)	08 Feb 2021 19:46:46

US3312637

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:05

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:53:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:49:08
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered empty.	Karol Moore (b) (4)	08 Feb 2021 19:46:46

US3312637

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:53:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:49:14
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Yes (Y)'	Karol Moore (b) (4)	26 Feb 2021 20:54:24

US3312637

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:53:52
User entered 'I'	System	26 Feb 2021 20:54:24

US3312637

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:53:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:30:03
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Mar 2021 19:08:34

US3312637

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:05

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:53:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:30:03
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '05 Mar 2021'	(b) (4), (b) (6)	09 Mar 2021 19:08:34

US3312637

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:53:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:30:03
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	09 Mar 2021 19:08:34



US3312637

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:05

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:53:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:30:03
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered empty.	(b) (4), (b) (6)	09 Mar 2021 19:08:34

US3312637

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:53:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:30:10
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Mar 2021 19:08:39

US3312637

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:53:52
User entered 'I'	System	09 Mar 2021 19:08:39

**US3312637**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:06:05**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Mar 2021 16:22:31

US3312637

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:05

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
User entered '31 Mar 2021'	(b) (4), (b) (6)	31 Mar 2021 16:22:31

US3312637

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:05

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	31 Mar 2021 16:22:31

**US3312637**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:06:05**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	31 Mar 2021 16:22:31

US3312637

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
User entered 'No (N)'	(b) (4), (b) (6)	31 Mar 2021 16:22:38



US3312637

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 16:22:38

US3312637

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:05

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 16:22:38

**US3312637**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:06:05**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 16:22:38

US3312637

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:05

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 16:22:38

US3312637

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:05

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 16:22:38

US3312637

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:05

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 16:22:38

US3312637

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 16:22:38

**US3312637**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:06:05**

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 16:22:38



US3312637

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 16:22:38

US3312637

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 16:22:38

US3312637

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 16:22:38

US3312637

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 16:22:38

US3312637

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 16:22:38

US3312637

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:05

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 16:22:38

US3312637

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:06:05

Was the physical examination performed?

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
User entered 'No (N)'	(b) (4), (b) (6)	31 Mar 2021 16:22:41

US3312637

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:06:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 16:22:41



US3312637

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Mar 2021 16:22:51

US3312637

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:05

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
User entered '31 Mar 2021'	(b) (4), (b) (6)	31 Mar 2021 16:22:51

US3312637

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:05

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
User entered '09:48'	(b) (4), (b) (6)	31 Mar 2021 16:22:51

**US3312637**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:06:05**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '31 Mar 2021 09:48'	System	31 Mar 2021 16:22:51

US3312637

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:20:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Mar 2021 16:22:54

**US3312637**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:06:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Mar 2021 16:22:54

US3312637

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:30:52
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Jan 2021 17:43:43

US3312637

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:05

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:30:52
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '21 Jan 2021'	(b) (4), (b) (6)	27 Jan 2021 17:43:43



US3312637

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:05

[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 13:13:06
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:30:52
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	27 Jan 2021 17:43:43

US3312637

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:05

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
User entered 'UNBLND_DECIDE'	System	27 Jan 2021 17:43:43

US3312637

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:06:05

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:31:09
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '21 Jan 2021'	(b) (4), (b) (6)	27 Jan 2021 17:58:35

**US3312637**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:06:05**

[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 13:13:06
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 15:02:11

US3312637

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:06:05

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:31:09
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Jan 2021 17:58:35

US3312637

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:06:05

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 15:02:11

US3312637

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:06:05

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:31:09
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '21 Jan 2021'	(b) (4), (b) (6)	27 Jan 2021 17:58:35

US3312637

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:06:05

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:31:09
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	27 Jan 2021 17:58:35



US3312637

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:06:05

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:31:09
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	27 Jan 2021 17:58:35

US3312637

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:06:05

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:31:09
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Not Administered (NA)'	(b) (4), (b) (6)	27 Jan 2021 17:58:35

US3312637

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:06:05

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:31:09
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Jan 2021 17:58:35

US3312637

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:06:05

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
User entered empty.	System	27 Jan 2021 17:58:35

US3312637

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:06:05

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
User entered 'I'	System	27 Jan 2021 17:58:35

US3312637

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:06:05

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:32:52
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered missing code ND - Not Done.	(b) (4), (b) (6)	27 Jan 2021 18:06:29

US3312637

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:06:05

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:32:52
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered missing code ND - Not Done.	(b) (4), (b) (6)	27 Jan 2021 18:06:29

US3312637

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:06:05

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
User entered empty.	System	27 Jan 2021 18:06:29
DataPoint set to visible.	System	27 Jan 2021 17:58:35



US3312637

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:06:05

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:32:52
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered missing code ND - Not Done.	(b) (4), (b) (6)	27 Jan 2021 18:06:29

US3312637

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:06:05

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:32:52
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered missing code ND - Not Done.	(b) (4), (b) (6)	27 Jan 2021 18:06:29

US3312637

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:06:05

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
User entered empty.	System	27 Jan 2021 18:06:29
DataPoint set to visible.	System	27 Jan 2021 17:58:35

US3312637

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	27 Jan 2021 18:06:29

US3312637

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:32:52
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Jan 2021 18:06:29

US3312637

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:32:52
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '21 Jan 2021'	(b) (4), (b) (6)	27 Jan 2021 18:06:29

US3312637

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:05

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:32:52
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '12:15'	(b) (4), (b) (6)	27 Jan 2021 18:06:29

US3312637

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
User entered '21 Jan 2021 12:15'	System	27 Jan 2021 18:06:29



US3312637

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:32:52
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '98.3' F	(b) (4), (b) (6)	27 Jan 2021 18:06:29

US3312637

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:32:52
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Oral (Oral)'	(b) (4), (b) (6)	27 Jan 2021 18:06:29

US3312637

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:32:52
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered empty.	(b) (4), (b) (6)	27 Jan 2021 18:06:29

US3312637

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:32:52
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '76'	(b) (4), (b) (6)	27 Jan 2021 18:06:29

US3312637

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
User entered 'bpm'	System	27 Jan 2021 18:06:29

US3312637

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:32:52
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '16'	(b) (4), (b) (6)	27 Jan 2021 18:06:29

US3312637

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
User entered 'breaths/min'	System	27 Jan 2021 18:06:29

US3312637

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:32:52
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '144'	(b) (4), (b) (6)	27 Jan 2021 18:06:29



US3312637

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
User entered 'mmHg'	System	27 Jan 2021 18:06:29

US3312637

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:05

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:32:52
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '81'	(b) (4), (b) (6)	27 Jan 2021 18:06:29

US3312637

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
User entered 'mmHg'	System	27 Jan 2021 18:06:29

US3312637

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:06:05

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:32:52
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered missing code ND - Not Done.	(b) (4), (b) (6)	27 Jan 2021 18:06:29

US3312637

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:06:05

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:32:52
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered missing code ND - Not Done.	(b) (4), (b) (6)	27 Jan 2021 18:06:29

US3312637

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:06:05

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
User entered empty.	System	27 Jan 2021 18:06:29
DataPoint set to visible.	System	27 Jan 2021 17:58:35

US3312637

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	27 Jan 2021 18:06:29

US3312637

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:32:52
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Jan 2021 18:06:29



US3312637

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:32:52
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '21 Jan 2021'	(b) (4), (b) (6)	27 Jan 2021 18:06:29

US3312637

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:05

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:32:52
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '13:45'	(b) (4), (b) (6)	27 Jan 2021 18:06:29

US3312637

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
User entered '21 Jan 2021 13:45'	System	27 Jan 2021 18:06:29

US3312637

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:32:52
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '97.6' F	(b) (4), (b) (6)	27 Jan 2021 18:06:29

US3312637

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:32:52
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Oral (Oral)'	(b) (4), (b) (6)	27 Jan 2021 18:06:29

US3312637

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:32:52
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered empty.	(b) (4), (b) (6)	27 Jan 2021 18:06:29

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:32:52
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '84'	(b) (4), (b) (6)	27 Jan 2021 18:06:29

US3312637

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
User entered 'bpm'	System	27 Jan 2021 18:06:29



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:32:52
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '16'	(b) (4), (b) (6)	27 Jan 2021 18:06:29

US3312637

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
User entered 'breaths/min'	System	27 Jan 2021 18:06:29

US3312637

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:32:52
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '140'	(b) (4), (b) (6)	27 Jan 2021 18:06:29

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
User entered 'mmHg'	System	27 Jan 2021 18:06:29

US3312637

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:32:52
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '83'	(b) (4), (b) (6)	27 Jan 2021 18:06:29

US3312637

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
User entered 'mmHg'	System	27 Jan 2021 18:06:29

US3312637

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:06:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:33:27
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Jan 2021 18:06:41

US3312637

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:06:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:33:27
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User closed query 'Was the physical examination performed is Yes, however Date of examination is missing. Please provide.' (Site from System).	System	27 Jan 2021 18:07:01
User entered '21 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Jan 2021 18:07:01
User opened query 'Was the physical examination performed is Yes, however Date of examination is missing. Please provide.' (Site from System).	System	27 Jan 2021 18:06:41
User entered empty.	(b) (4), (b) (6)	27 Jan 2021 18:06:41



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:05

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:33:40
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Jan 2021 18:07:17

US3312637

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:05

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:33:40
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered empty.	(b) (4), (b) (6)	27 Jan 2021 18:07:17

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:05

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 13:13:06
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:33:40
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered empty.	(b) (4), (b) (6)	27 Jan 2021 18:07:17

US3312637

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:05

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
User entered 'mRNA-1273'	System	27 Jan 2021 18:07:17
DataPoint set to visible.	System	27 Jan 2021 17:58:35

US3312637

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:05

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:33:40
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '21 Jan 2021'	(b) (4), (b) (6)	27 Jan 2021 18:07:17

US3312637

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:05

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:33:40
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '13:14'	(b) (4), (b) (6)	27 Jan 2021 18:07:17

US3312637

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:05

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
User entered '21 Jan 2021 13:14'	System	27 Jan 2021 18:07:17

US3312637

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:05

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:33:40
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	27 Jan 2021 18:07:17



US3312637

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:05

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:33:40
User entered 'ONCE'	System	27 Jan 2021 18:07:17

US3312637

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:05

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
User entered 'INTRAMUSCULAR'	System	27 Jan 2021 18:07:17

US3312637

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:09
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Jan 2021 17:59:33

US3312637

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:05

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:09
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '21 Jan 2021'	(b) (4), (b) (6)	27 Jan 2021 17:59:33

US3312637

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:05

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:09
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '11:54'	(b) (4), (b) (6)	27 Jan 2021 17:59:33

US3312637

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
User entered '21 Jan 2021 11:54'	System	27 Jan 2021 17:59:33

US3312637

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:06:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Jan 2021 17:59:44

US3312637

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:06:05

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '21 Jan 2021'	(b) (4), (b) (6)	27 Jan 2021 17:59:44



US3312637

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:06:05

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:15
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '11:53'	(b) (4), (b) (6)	27 Jan 2021 17:59:44

US3312637

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:06:05

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
User entered '21 Jan 2021 11:53'	System	27 Jan 2021 17:59:44

US3312637

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:19
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Jan 2021 17:59:48

US3312637

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:06
User entered '1'	System	27 Jan 2021 17:59:48

US3312637

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:57
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:50:45
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	01 Feb 2021 20:49:55
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	01 Feb 2021 20:49:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Feb 2021 20:49:50

**US3312637**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:06:05**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:57
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:50:45
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '28 Jan 2021'	(b) (4), (b) (6)	01 Feb 2021 20:49:50

US3312637

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:57
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:50:45
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	01 Feb 2021 20:49:55
reason for change: Data Entry Error		
User entered empty.	(b) (4), (b) (6)	01 Feb 2021 20:49:50

US3312637

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:05

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:57
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:50:45
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered empty.	(b) (4), (b) (6)	01 Feb 2021 20:49:50



**US3312637**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:06:05**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:57
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:50:52
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Feb 2021 20:49:59

**US3312637**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:06:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:57
User entered 'I'	System	01 Feb 2021 20:49:59

**US3312637**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:06:05**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:40:57
User entered '1'	System	01 Feb 2021 20:49:59
DataPoint set to visible.	System	01 Feb 2021 20:49:59

**US3312637**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:06:05**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:57
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:51:07
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Feb 2021 14:40:01

**US3312637**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:06:05**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:57
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:51:07
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '18 Feb 2021'	(b) (4), (b) (6)	22 Feb 2021 14:40:01

US3312637

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:05

[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 15:53:57
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:51:07
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Home (Home)'	(b) (4), (b) (6)	22 Feb 2021 14:40:01

**US3312637**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:06:05**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:57
User entered 'OLD29'	System	22 Feb 2021 14:40:01

US3312637

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:57
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:51:16
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Feb 2021 14:41:09



**US3312637**

**Folder: OL-D29 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:06:05**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:57
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:51:16
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '18 Feb 2021'	(b) (4), (b) (6)	22 Feb 2021 14:41:09

**US3312637**

**Folder: OL-D29 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:06:05**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:57
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:51:16
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '11:16'	(b) (4), (b) (6)	22 Feb 2021 14:41:09

**US3312637**

**Folder: OL-D29 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:06:05**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:57
User entered '18 Feb 2021 11:16'	System	22 Feb 2021 14:41:09

US3312637

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:57
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:51:16
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '98.0' F	(b) (4), (b) (6)	22 Feb 2021 14:41:09

**US3312637**

**Folder: OL-D29 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:06:05**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:57
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:51:16
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Oral (Oral)'	(b) (4), (b) (6)	22 Feb 2021 14:41:09

**US3312637**

**Folder: OL-D29 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:06:05**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:57
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:51:16
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 14:41:09

**US3312637**

**Folder: OL-D29 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:06:05**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:57
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:51:16
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '100'	(b) (4), (b) (6)	22 Feb 2021 14:41:09

**US3312637**

**Folder: OL-D29 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:06:05**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:57
User entered 'bpm'	System	22 Feb 2021 14:41:09



US3312637

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:57
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:51:16
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '14'	(b) (4), (b) (6)	22 Feb 2021 14:41:09

US3312637

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:57
User entered 'breaths/min'	System	22 Feb 2021 14:41:09

**US3312637**

**Folder: OL-D29 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:06:05**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:57
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:51:16
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '124'	(b) (4), (b) (6)	22 Feb 2021 14:41:09

**US3312637**

**Folder: OL-D29 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:06:05**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:57
User entered 'mmHg'	System	22 Feb 2021 14:41:09

**US3312637**

**Folder: OL-D29 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:06:05**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:57
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:51:16
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '82'	(b) (4), (b) (6)	22 Feb 2021 14:41:09

**US3312637**

**Folder: OL-D29 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:06:05**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:57
User entered 'mmHg'	System	22 Feb 2021 14:41:09

US3312637

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:05

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:57

US3312637

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:05

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:57



US3312637

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:06:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:57
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:51:33
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Feb 2021 14:41:14

US3312637

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:06:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:57
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:51:33
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User closed query 'Was the physical examination performed is Yes, however Date of examination is missing. Please provide.' (Site from System).	System	22 Feb 2021 14:41:22
User entered '18 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Feb 2021 14:41:22
User opened query 'Was the physical examination performed is Yes, however Date of examination is missing. Please provide.' (Site from System).	System	22 Feb 2021 14:41:14
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 14:41:14

**US3312637**

**Folder: OL-D29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:06:05**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:57
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:51:42
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Feb 2021 14:41:40

US3312637

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:05

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:57
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:51:42
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '18 Feb 2021'	(b) (4), (b) (6)	22 Feb 2021 14:41:40

**US3312637**

**Folder: OL-D29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:06:05**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:57
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:51:42
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '11:35'	(b) (4), (b) (6)	22 Feb 2021 14:41:40

**US3312637**

**Folder: OL-D29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:06:05**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:57
User entered '18 Feb 2021 11:35'	System	22 Feb 2021 14:41:40

**US3312637**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 09 Jun 2021 17:06:05**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:26:16
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:59
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:11:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 19:52:04

**US3312637**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:06:05**

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 15:13:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:11:13
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:11:43
User entered 'USA-US300-2020-mRNA-1273-P301000006'	System	21 Oct 2020 18:11:37
User entered 'New'	(b) (4), (b) (6)	21 Oct 2020 18:11:37



US3312637

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:05

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 15:13:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:11:13
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 aggravated - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 05:37:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 05:37:51
Data point term sent to Coder	System	10 Nov 2020 19:47:37
Coding entries removed.	(b) (4), (b) (6)	10 Nov 2020 19:47:01
User entered 'exacerbation of CORONARY ARTERY DISEASE' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 19:47:01
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.	Coder Import (b) (4)	20 Oct 2020 19:59:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 19:59:38
Data point term sent to Coder	System	20 Oct 2020 19:58:28
User entered 'coronary artery disease'	(b) (4), (b) (6)	20 Oct 2020 19:58:21

**US3312637**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:06:05**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 15:13:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:11:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 19:58:21

US3312637

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:05

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 15:13:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:11:13
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 19:58:21

US3312637

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:05

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 15:13:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:11:13
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 19:58:21

**US3312637**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:06:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 15:13:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:11:13
User entered '15 Oct 2020'	(b) (4), (b) (6)	20 Oct 2020 19:58:21

**US3312637**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:06:05**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 15:13:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:11:13
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 19:58:21

**US3312637**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:06:05**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 19:58:21

US3312637

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:05

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 15:13:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:11:13
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 19:58:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Oct 2020 19:58:41
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Oct 2020 19:58:41
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 19:58:21
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 19:58:21



**US3312637**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:06:05**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 15:13:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:11:13
User entered '16 Oct 2020'	(b) (4), (b) (6)	20 Oct 2020 19:58:21

**US3312637**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:06:05**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 15:13:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:11:13
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 19:58:21

**US3312637**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:06:05**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 19:58:21

US3312637

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:05

Severity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 15:13:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:11:13
User closed query 'PV Query: Since the subject was hospitalized for the event of coronary artery disease, please consider updating the severity of the event to Grade 4. If the severity is to remain grade 2, please clarify/explain. ' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 00:14:05
Query 'PV Query: Since the subject was hospitalized for the event of coronary artery disease, please consider updating the severity of the event to Grade 4. If the severity is to remain grade 2, please clarify/explain. ' answered with 'confirmed. correct as entered. grade 2 per PI' (Site from Safety).	Karol Moore (b) (4)	04 Nov 2020 20:52:05
User opened query 'PV Query: Since the subject was hospitalized for the event of coronary artery disease, please consider updating the severity of the event to Grade 4. If the severity is to remain grade 2, please clarify/explain. ' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 17:24:48
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	20 Oct 2020 19:58:21

US3312637

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 15:13:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:11:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 19:58:21

**US3312637**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:06:05**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 15:13:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:11:13
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 19:58:21

**US3312637**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:06:05**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 15:13:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:11:13
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 19:58:21

**US3312637**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:06:05**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 15:13:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:11:13
User entered 'I'	(b) (4), (b) (6)	20 Oct 2020 19:58:21



US3312637

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:05

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 15:13:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:11:13
User entered '15 Oct 2020'	(b) (4), (b) (6)	20 Oct 2020 19:58:21

US3312637

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:05

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 15:13:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:11:13
User entered '16 Oct 2020'	(b) (4), (b) (6)	20 Oct 2020 19:58:21

**US3312637**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:06:05**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 15:13:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:11:13
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 19:58:21

**US3312637**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:06:05**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 15:13:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:11:13
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 19:58:21

**US3312637**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:06:05**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 15:13:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:11:13
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 19:58:21

**US3312637**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:06:05**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 15:13:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:11:13
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 19:58:21

US3312637

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:05

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 15:13:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:11:13
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 19:58:21

US3312637

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:05

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 15:13:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:11:13
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	20 Oct 2020 19:58:21



US3312637

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:05

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 15:13:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:11:13
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	20 Oct 2020 19:58:21

US3312637

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:05

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 15:13:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:11:13
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	21 Dec 2020 15:42:23
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered by data change (Site from System).	System	21 Dec 2020 15:42:23
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	15 Dec 2020 21:50:49
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	(b) (4), (b) (6)	20 Oct 2020 19:58:21

**US3312637**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:06:05**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 15:13:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:11:13
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 19:58:21

**US3312637**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:06:05**

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 15:13:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:11:13
User entered 'I'	(b) (4), (b) (6)	20 Oct 2020 19:58:21

**US3312637**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:06:05**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 15:13:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:11:13
User entered 'I'	(b) (4), (b) (6)	20 Oct 2020 19:58:21

**US3312637**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:06:05**

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 15:13:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:11:13
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	20 Oct 2020 19:58:21

**US3312637**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:06:05**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 15:13:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:11:13
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 19:58:21

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:05

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 15:13:29
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:11:13
User closed query ' PV Query: Please provide the results and type of testing for COVID-19 test done on 12 Oct 2020 during pre-admission, and 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)	23 Nov 2020 15:20:53
Query ' PV Query: Please provide the results and type of testing for COVID-19 test done on 12 Oct 2020 during pre-admission, and any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' answered with 'Covid nasal swab done 12Oct2020 during preadmission, exact type unknown- not included in medical record and subject did not know. No further COVID testing done!' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 21:20:23
User opened query ' PV Query: Please provide the results and type of testing for COVID-19 test done on 12 Oct 2020 during pre-admission, and 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)	20 Nov 2020 18:59:46
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)	20 Nov 2020 18:59:46
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results, including cardiac stress test date and results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 18:50:04



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:05

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results, including cardiac stress test date and results. Please include units and reference ranges if applicable.' answered with 'Please see query response 10Nov2020, already answered' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 17:41:47
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 'Query answered previously, see query response Nov102020' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 17:41:05
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)	13 Nov 2020 19:38:14
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results, including cardiac stress test date and results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 19:38:06
User closed query 'PV Query: Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). ' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 21:52:05
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results, including cardiac stress test date and results. Please include units and reference ranges if applicable. ' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 21:51:57
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)	11 Nov 2020 21:51:52
Query 'PV Query: Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). ' answered with 'CM updated' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 16:29:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:05

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT IS A 58 YEAR OLD GENTLEMAN WITH H/O SARCOIDOSIS, UMBILICAL HERNIA, HYPERCHOLESTEROLEMIA, HYPERTENSION, SVT AND ANGINA WHO WAS HOSPITALIZED AFTER CARDIAC CATHETERIZATION WITH STENT PLACEMENT, 10/15/2020-10/16/2020.  SUBJECT WAS SEEN ON 10/9/2020 FOR HIS D29 VISIT AT WHICH TIME HE DISCLOSED PLANS FOR UMBILICAL HERNIA REPAIR LEADING TO PRE-OPERATIVE TESTING, INCLUDING STRESS TEST WHICH WAS ABNORMAL AND WHICH LEAD TO PLANS FOR CARDIAC CATHETERIZATION (SCHEDULED FOR THE FOLLOWING WEEK). ON 10/19/2020, SUBJECT REPORTED (VIA TELEPHONE) THAT CARDIAC CATHETERIZATION WITH STENT PLACEMENT TOOK PLACE ON 10/15/2020. HE WAS HOSPITALIZED POST-OPERATIVELY, OVERNIGHT, AND DISCHARGED ON 10/16/2020. HE DENIES ANY COMPLICATIONS AND REPORTED FEELING WELL AT LAST CONTACT. HE WAS DISCHARGED ON ASPIRIN 325MG PO QD, ROSUVASTATIN 40MG PO QD, FAMOTIDINE 20MG PO QD, AND PRASUGREL 10MG PO QD. PRIOR TO CARDIAC CATHETERIZATION HE HAD STARTED PRN SUBLINGUAL NITROGLYCERIN. HE PLANS TO CONTINUE FOLLOW-UP WITH HIS CARDIOLOGIST.  IT IS NOTED THAT SUBJECT DID NOT DISCLOSE CARDIAC HISTORY OR UMBILICAL HERNIA AT SCREENING/D1 VISIT. ON 10/9/2020, HE DID REPORT THAT UMBILICAL SURGICAL REPAIR WHICH HAS NOT TAKEN PLACE WAS PLANNED PRE-STUDY ENROLLMENT AND THAT HERNIA HAS NOT WORSENED. LIKEWISE, HE REPORTED ANGINA HAD BEEN PRESENT FOR TWO YEARS AND WHILE IT HAD PROGRESSIVELY	(b) (4), (b) (6)	10 Nov 2020 16:29:47

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:05

[Narrative](#)

Audit	User	Time (GMT)
WORSENER OVERALL SINCE ONSET, IT HAD NOT WORSENER AFTER STUDY ENROLLMENT.  THIS IS AN SAE, HOSPITALIZATION, NOT RELATED TO IP. MEDICAL RECORDS WILL BE REQUESTED UPON RECEIPT OF SIGNED MEDICAL RECORDS RELEASE FROM SUBJECT.med recs reviewed:HAD PRE-SURGICAL WORK-UP WITH CARDIAC STRESS ECHO THAT LEAD TO CARDIAC CATHETERIZATION WHICH SHOWED SIGNIFICANT CORONARY ARTERY DISEASE IN LEFT ANTERIOR DESCENDING (LAD) ARTERY AND MODERATE IN THE LEFT CIRCUMFLEX AND RIGHT CORONARY ARTERIES. THE LAD WAS STENTED 15OCT2020. SUBJECT HAS DONE WELL POST PROCEDURE AND HAS HAD NO PROBLEMS, cardiac exam good at last visit' reason for change: Data Entry Error		

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:05

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT IS A 58 YEAR OLD GENTLEMAN WITH H/O SARCOIDOSIS, UMBILICAL HERNIA, HYPERCHOLESTEROLEMIA, HYPERTENSION, SVT AND ANGINA WHO WAS HOSPITALIZED AFTER CARDIAC CATHETERIZATION WITH STENT PLACEMENT, 10/15/2020-10/16/2020.  SUBJECT WAS SEEN ON 10/9/2020 FOR HIS D29 VISIT AT WHICH TIME HE DISCLOSED PLANS FOR UMBILICAL HERNIA REPAIR LEADING TO PRE-OPERATIVE TESTING, INCLUDING STRESS TEST WHICH WAS ABNORMAL AND WHICH LEAD TO PLANS FOR CARDIAC CATHETERIZATION (SCHEDULED FOR THE FOLLOWING WEEK). ON 10/19/2020, SUBJECT REPORTED (VIA TELEPHONE) THAT CARDIAC CATHETERIZATION WITH STENT PLACEMENT TOOK PLACE ON 10/15/2020. HE WAS HOSPITALIZED POST-OPERATIVELY, OVERNIGHT, AND DISCHARGED ON 10/16/2020. HE DENIES ANY COMPLICATIONS AND REPORTED FEELING WELL AT LAST CONTACT. HE WAS DISCHARGED ON ASPIRIN 325MG PO QD, ROSUVASTATIN 40MG PO QD, FAMOTIDINE 20MG PO QD, AND PRASUGREL 10MG PO QD. PRIOR TO CARDIAC CATHETERIZATION HE HAD STARTED PRN SUBLINGUAL NITROGLYCERIN. HE PLANS TO CONTINUE FOLLOW-UP WITH HIS CARDIOLOGIST.  IT IS NOTED THAT SUBJECT DID NOT DISCLOSE CARDIAC HISTORY OR UMBILICAL HERNIA AT SCREENING/D1 VISIT. ON 10/9/2020, HE DID REPORT THAT UMBILICAL SURGICAL REPAIR WHICH HAS NOT TAKEN PLACE WAS PLANNED PRE-STUDY ENROLLMENT AND THAT HERNIA HAS NOT WORSENER. LIKEWISE, HE REPORTED ANGINA HAD BEEN PRESENT FOR TWO YEARS AND WHILE IT HAD PROGRESSIVELY	(b) (4), (b) (6)	10 Nov 2020 16:28:34

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:05

[Narrative](#)

Audit	User	Time (GMT)
WORSENER OVERALL SINCE ONSET, IT HAD NOT WORSENER AFTER STUDY ENROLLMENT.  THIS IS AN SAE, HOSPITALIZATION, NOT RELATED TO IP. MEDICAL RECORDS WILL BE REQUESTED UPON RECEIPT OF SIGNED MEDICAL RECORDS RELEASE FROM SUBJECT.had pre-surgical work-up with cardiac stress echo that lead to cardiac catheterization which showed significant coronary artery disease in left anterior descending (LAD) artery and moderate in the left circumflex and right coronary arteries. The LAD was stented 15Oct2020. Subject has done well post procedure and has had no problems' reason for change: Data Entry Error		
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' answered with 'COVID 19 test done 10/12/2020 pre admission' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 16:27:32
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results, including cardiac stress test date and results. Please include units and reference ranges if applicable. ' answered with 'Cardiac stress test and echo done: abnormal, date unknown but before 09Oct2020' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 16:25:07
User closed query 'PV Query: Please add concomitant medication, sublingual nitroglycerin, reported in the narrative to the concomitant medication eCRF. ' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 00:14:19
User closed query 'PV Query: Please confirm if umbilical hernia, hypercholesterolemia, hypertension, SVT, and angina are considered medical history (prior to start of study). If considered MH, please add to MH eCRF. If any of the events are a new finding, please assess whether it meets criteria for separate AE/SAE reporting. ' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 00:14:16

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please confirm if umbilical hernia, hypercholesterolemia, hypertension, SVT, and angina are considered medical history (prior to start of study). If considered MH, please add to MH eCRF. If any of the events are a new finding, please assess whether it meets criteria for separate AE/SAE reporting. ' answered with ' PRESENT ON MED HISTORY ALREADY' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 00:36:26
Query 'PV Query: Please add concomitant medication, sublingual nitroglycerin, reported in the narrative to the concomitant medication eCRF. ' answered with 'updated' (Site from Safety).	Karol Moore (b) (4)	04 Nov 2020 20:52:35
User opened query 'PV Query: Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). ' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 17:24:20
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results, including cardiac stress test date and results. Please include units and reference ranges if applicable. ' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 17:23:45
User opened query 'PV Query: Please add concomitant medication, sublingual nitroglycerin, reported in the narrative to the concomitant medication eCRF. ' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 17:23:04
User opened query 'PV Query: Please confirm if umbilical hernia, hypercholesterolemia, hypertension, SVT, and angina are considered medical history (prior to start of study). If considered MH, please add to MH eCRF. If any of the events are a new finding, please assess whether it meets criteria for separate AE/SAE reporting. ' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 17:22:40
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)	30 Oct 2020 17:22:05

US3312637

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:05

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Subject is a 58 year old gentleman with h/o sarcoidosis, umbilical hernia, hypercholesterolemia, hypertension, SVT and angina who was hospitalized after cardiac catheterization with stent placement, 10/15/2020-10/16/2020.  Subject was seen on 10/9/2020 for his D29 visit at which time he disclosed plans for umbilical hernia repair leading to pre-operative testing, including stress test which was abnormal and which lead to plans for cardiac catheterization (scheduled for the following week). On 10/19/2020, subject reported (via telephone) that cardiac catheterization with stent placement took place on 10/15/2020. He was hospitalized post-operatively, overnight, and discharged on 10/16/2020. He denies any complications and reported feeling well at last contact. He was discharged on aspirin 325mg PO QD, rosuvastatin 40mg PO QD, famotidine 20mg PO QD, and prasugrel 10mg PO QD. Prior to cardiac catheterization he had started PRN sublingual nitroglycerin. He plans to continue follow-up with his cardiologist.  It is noted that subject did not disclose cardiac history or umbilical hernia at screening/D1 visit. On 10/9/2020, he did report that umbilical surgical repair which has not taken place was planned pre-study enrollment and that hernia has not worsened. Likewise, he reported angina had been present for two years and while it had progressively worsened overall since onset, it had not worsened after study enrollment.  This is an SAE, hospitalization, not related to IP. Medical records will be requested upon receipt of signed medical records release from subject.'	(b) (4), (b) (6)	20 Oct 2020 19:58:21

**US3312637**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:06:05**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 19:58:21



**US3312637**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:06:05**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 19:58:21

**US3312637**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:06:05**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	20 Oct 2020 19:58:21

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:06:05

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:26:16
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:36:27
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User closed query 'Per ETRTR: According to SAE "Coronary Artery Disease", Concomitant procedure was performed. Please add ConProcedure within respective page, thanks.' (Site from CRA).	(b) (4), (b) (6)	15 Nov 2020 20:59:46
User closed query 'Per ETRTR: Please add or confirm medication dosed for SAE "Coronary Artery Disease", thanks.' (Site from CRA).	(b) (4), (b) (6)	15 Nov 2020 20:59:39
Query 'Per ETRTR: According to SAE "Coronary Artery Disease", Concomitant procedure was performed. Please add ConProcedure within respective page, thanks.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 16:38:51
Query 'Per ETRTR: Please add or confirm medication dosed for SAE "Coronary Artery Disease", thanks.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 16:38:43
User opened query 'Per ETRTR: According to SAE "Coronary Artery Disease", Concomitant procedure was performed. Please add ConProcedure within respective page, thanks.' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 20:00:23
User opened query 'Per ETRTR: Please add or confirm medication dosed for SAE "Coronary Artery Disease", thanks.' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 19:59:38
User entered 'Yes (Y)'	Karol Moore (b) (4)	30 Sep 2020 23:21:22

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:06:05

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: FLUOXETINE HYDROCHLORIDE, PRODUCTSYNONYM: FLUOXETIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 06:23:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 06:23:41
Data point term sent to Coder	System	30 Sep 2020 23:22:51
User entered 'fluoxetine'	Karol Moore (b) (4)	30 Sep 2020 23:21:51

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:06:05

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'No (N)'	Karol Moore (b) (4)	30 Sep 2020 23:21:51

**US3312637**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:06:05**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'depression'	Karol Moore (b) (4)	30 Sep 2020 23:21:51

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:06:05

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '20'	Karol Moore (b) (4)	30 Sep 2020 23:21:51

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:06:05

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'mg (mg)'	Karol Moore (b) (4)	30 Sep 2020 23:21:51



US3312637

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:06:05**

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered empty.	Karol Moore (b) (4)	30 Sep 2020 23:21:51

US3312637

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:06:05**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'once daily (QD)'	Karol Moore (b) (4)	30 Sep 2020 23:21:51

US3312637

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:06:05**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered empty.	Karol Moore (b) (4)	30 Sep 2020 23:21:51

**US3312637**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:06:05**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Oral (ORAL)'	Karol Moore (b) (4)	30 Sep 2020 23:21:51

US3312637

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:06:05**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered empty.	Karol Moore (b) (4)	30 Sep 2020 23:21:51

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:06:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'un UNK 2001'	Karol Moore (b) (4)	30 Sep 2020 23:21:51

US3312637

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:06:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '0'	Karol Moore (b) (4)	30 Sep 2020 23:21:51

**US3312637**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:06:05**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Yes (Y)'	Karol Moore (b) (4)	30 Sep 2020 23:21:51



**US3312637**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:06:05**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered empty.	Karol Moore (b) (4)	30 Sep 2020 23:21:51

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:06:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'No (N)'	Karol Moore (b) (4)	30 Sep 2020 23:21:51

**US3312637**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:06:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 23:21:51

US3312637

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:06:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 23:21:51

US3312637

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:06:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Sep 2020 23:21:51

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:06:05

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Sep 2020 23:23:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Sep 2020 23:23:42
Data point term sent to Coder	System	30 Sep 2020 23:22:49
User entered 'omeprazole'	Karol Moore (b) (4)	30 Sep 2020 23:22:13

**US3312637**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:06:05**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'No (N)'	Karol Moore (b) (4)	30 Sep 2020 23:22:13

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:06:05

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Gastroesophageal reflux disease'	Karol Moore (b) (4)	30 Sep 2020 23:22:13



US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:06:05

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '20'	Karol Moore (b) (4)	30 Sep 2020 23:22:13

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:06:05

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'mg (mg)'	Karol Moore (b) (4)	30 Sep 2020 23:22:13

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:06:05

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered empty.	Karol Moore (b) (4)	30 Sep 2020 23:22:13

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:06:05

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'once daily (QD)'	Karol Moore (b) (4)	30 Sep 2020 23:22:13

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:06:05

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered empty.	Karol Moore (b) (4)	30 Sep 2020 23:22:13

**US3312637**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:06:05**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Oral (ORAL)'	Karol Moore (b) (4)	30 Sep 2020 23:22:13

US3312637

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:06:05**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered empty.	Karol Moore (b) (4)	30 Sep 2020 23:22:13

**US3312637**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:06:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'un UNK 2001'	Karol Moore (b) (4)	30 Sep 2020 23:22:13



US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:06:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '0'	Karol Moore (b) (4)	30 Sep 2020 23:22:13

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:06:05

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Yes (Y)'	Karol Moore (b) (4)	30 Sep 2020 23:22:13

US3312637

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:06:05**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered empty.	Karol Moore (b) (4)	30 Sep 2020 23:22:13

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:06:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'No (N)'	Karol Moore (b) (4)	30 Sep 2020 23:22:13

US3312637

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:06:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 23:22:13

US3312637

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:06:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 23:22:13

US3312637

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:06:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Sep 2020 23:22:13

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:06:05

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User coded data point as ATC: VARIOUS, ATC: ALL OTHER NON-THERAPEUTIC PRODUCTS, ATC: ALL OTHER NON-THERAPEUTIC PRODUCTS, PRODUCT: ALL OTHER NON-THERAPEUTIC PRODUCTS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Sep 2020 23:24:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Sep 2020 23:24:43
Data point term sent to Coder	System	30 Sep 2020 23:23:52
User entered 'cpap'	Karol Moore (b) (4)	30 Sep 2020 23:22:52



US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:06:05

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'No (N)'	Karol Moore (b) (4)	30 Sep 2020 23:22:52

**US3312637**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:06:05**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'sleep apnea'	Karol Moore (b) (4)	30 Sep 2020 23:22:52

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:06:05

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'I'	Karol Moore (b) (4)	30 Sep 2020 23:22:52

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:06:05

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Other (OTHER)'	Karol Moore (b) (4)	30 Sep 2020 23:22:52

US3312637

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:06:05**

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'unit'	Karol Moore (b) (4)	30 Sep 2020 23:22:52

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:06:05

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'other (OTHER)'	Karol Moore (b) (4)	30 Sep 2020 23:22:52

US3312637

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:06:05**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'nightly at bedtime'	Karol Moore (b) (4)	30 Sep 2020 23:22:52

**US3312637**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:06:05**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Nasal (NASAL)'	Karol Moore (b) (4)	30 Sep 2020 23:22:52



US3312637

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:06:05**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered empty.	Karol Moore (b) (4)	30 Sep 2020 23:22:52

US3312637

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:06:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'un UNK 2015'	Karol Moore (b) (4)	30 Sep 2020 23:22:52

**US3312637**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:06:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '0'	Karol Moore (b) (4)	30 Sep 2020 23:22:52

**US3312637**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:06:05**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Yes (Y)'	Karol Moore (b) (4)	30 Sep 2020 23:22:52

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:06:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered empty.	Karol Moore (b) (4)	30 Sep 2020 23:22:52

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:06:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'No (N)'	Karol Moore (b) (4)	30 Sep 2020 23:22:52

US3312637

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:06:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 23:22:52

US3312637

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:06:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 23:22:52



US3312637

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:06:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 23:22:52

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:06:05

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:22
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
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)	30 Sep 2020 23:24:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Sep 2020 23:24:43
Data point term sent to Coder	System	30 Sep 2020 23:23:52
User entered 'acetaminophen'	Karol Moore (b) (4)	30 Sep 2020 23:23:23

**US3312637**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:06:05**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:22
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'No (N)'	Karol Moore (b) (4)	30 Sep 2020 23:23:23

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:06:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:22
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User closed query 'Per DM CLR: Please provide the specific location of MUSCLE ACHES (eg, generalized myalgia, back muscle pain, arms, etc). Review and update Indication.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 13:36:56
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the MUSCLE ACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of MUSCLE ACHES did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 05:55:31
Query 'Per DM CLR: Please provide the specific location of MUSCLE ACHES (eg, generalized myalgia, back muscle pain, arms, etc). Review and update Indication.' answered with 'PER PROTOCOL, SOLICITED SYMPTOM IS "GENERALIZED MUSCLE ACHES"' (Site from DM).	Karol Moore (b) (4)	25 Nov 2020 20:07:27

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:06:05

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the MUSCLE ACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of MUSCLE ACHES did not meet the AE reporting criteria.' answered with 'Muscle aches does not meet the AE reporting criteria' (Site from DM).	Kelly Moen (b) (4)	24 Nov 2020 21:42:19
User opened query 'Per DM CLR: Please provide the specific location of MUSCLE ACHES (eg, generalized myalgia, back muscle pain, arms, etc). Review and update Indication.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 14:23:00
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the MUSCLE ACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of MUSCLE ACHES did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 14:22:37
User entered 'muscle aches'	Karol Moore (b) (4)	30 Sep 2020 23:23:23

**US3312637**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:06:05**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:22
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '1000'	Karol Moore (b) (4)	30 Sep 2020 23:23:23

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:06:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:22
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'mg (mg)'	Karol Moore (b) (4)	30 Sep 2020 23:23:23

US3312637

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:06:05**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:22
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered empty.	Karol Moore (b) (4)	30 Sep 2020 23:23:23



**US3312637**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:06:05**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:22
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'as needed (PRN)'	Karol Moore (b) (4)	30 Sep 2020 23:23:23

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:06:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:22
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered empty.	Karol Moore (b) (4)	30 Sep 2020 23:23:23

**US3312637**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:06:05**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:22
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Oral (ORAL)'	Karol Moore (b) (4)	30 Sep 2020 23:23:23

US3312637

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:06:05**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:22
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered empty.	Karol Moore (b) (4)	30 Sep 2020 23:23:23

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:06:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:22
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '16 Sep 2020'	Karol Moore (b) (4)	30 Sep 2020 23:23:23

**US3312637**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:06:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:22
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '0'	Karol Moore (b) (4)	30 Sep 2020 23:23:23

**US3312637**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:06:05**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:22
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'No (N)'	Karol Moore (b) (4)	30 Sep 2020 23:23:23

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:06:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:22
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '16 Sep 2020'	Karol Moore (b) (4)	30 Sep 2020 23:23:23



US3312637

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:06:05**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:22
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Yes (Y)'	Karol Moore (b) (4)	30 Sep 2020 23:23:23

**US3312637**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:06:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:22
User entered empty.	System	30 Sep 2020 23:23:23

US3312637

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:06:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:22
User entered empty.	System	30 Sep 2020 23:23:23

US3312637

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:06:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:22
User entered empty.	System	30 Sep 2020 23:23:23

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:06:05

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
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.	Coder Import (b) (4) (b) (4)	04 Nov 2020 16:37:06
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 16:37:06
Data point term sent to Coder User entered 'nitroglycerin'	System Karol Moore (b) (4)	02 Nov 2020 15:47:49 02 Nov 2020 15:47:02

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:06:05

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'No (N)'	Karol Moore (b) (4)	02 Nov 2020 15:47:02

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:06:05

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'angina'	Karol Moore (b) (4)	02 Nov 2020 15:47:02

US3312637

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:06:05**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '0.3'	Karol Moore (b) (4)	02 Nov 2020 15:47:02



US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:06:05

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'mg (mg)'	Karol Moore (b) (4)	02 Nov 2020 15:47:02

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:06:05

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered empty.	Karol Moore (b) (4)	02 Nov 2020 15:47:02

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:06:05

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'as needed (PRN)'	Karol Moore (b) (4)	02 Nov 2020 15:47:02

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:06:05

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered empty.	Karol Moore (b) (4)	02 Nov 2020 15:47:02

**US3312637**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:06:05**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Other (OTHER)'	Karol Moore (b) (4)	02 Nov 2020 15:47:02

US3312637

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:06:05**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'sublingual'	Karol Moore (b) (4)	02 Nov 2020 15:47:02

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:06:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '09 Oct 2020'	Karol Moore (b) (4)	02 Nov 2020 15:47:02

**US3312637**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:06:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '0'	Karol Moore (b) (4)	02 Nov 2020 15:47:02



**US3312637**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:06:05**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Yes (Y)'	Karol Moore (b) (4)	02 Nov 2020 15:47:02

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:06:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered empty.	Karol Moore (b) (4)	02 Nov 2020 15:47:02

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:06:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'No (N)'	Karol Moore (b) (4)	02 Nov 2020 15:47:02

US3312637

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:06:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Nov 2020 15:47:02

US3312637

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:06:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Nov 2020 15:47:02

US3312637

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:06:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Nov 2020 15:47:02

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:06:05

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
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)	04 Nov 2020 16:37:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 16:37:12
Data point term sent to Coder	System	02 Nov 2020 15:47:49
User entered 'aspirin'	Karol Moore (b) (4)	02 Nov 2020 15:47:46

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:06:05

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Yes (Y)' reason for change: Data Entry Error	Karol Moore (b) (4)	21 Dec 2020 15:48:45
User entered 'No (N)'	Karol Moore (b) (4)	02 Nov 2020 15:47:46



US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:06:05

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User closed query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 11:58:18
Query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	Karol Moore (b) (4)	21 Dec 2020 15:48:50
User opened query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 07:04:08
User entered 'cardiac prophylaxis'	Karol Moore (b) (4)	02 Nov 2020 15:47:46

**US3312637**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:06:05**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '325'	Karol Moore (b) (4)	02 Nov 2020 15:47:46

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:06:05

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'mg (mg)'	Karol Moore (b) (4)	02 Nov 2020 15:47:46

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:06:05

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered empty.	Karol Moore (b) (4)	02 Nov 2020 15:47:46

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:06:05

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'once daily (QD)'	Karol Moore (b) (4)	02 Nov 2020 15:47:46

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:06:05

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered empty.	Karol Moore (b) (4)	02 Nov 2020 15:47:46

**US3312637**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:06:05**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Oral (ORAL)'	Karol Moore (b) (4)	02 Nov 2020 15:47:46

US3312637

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:06:05**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered empty.	Karol Moore (b) (4)	02 Nov 2020 15:47:46



**US3312637**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:06:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '16 Oct 2020'	Karol Moore (b) (4)	02 Nov 2020 15:47:46

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:06:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '0'	Karol Moore (b) (4)	02 Nov 2020 15:47:46

**US3312637**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:06:05**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Yes (Y)'	Karol Moore (b) (4)	02 Nov 2020 15:47:46

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:06:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered empty.	Karol Moore (b) (4)	02 Nov 2020 15:47:46

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:06:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'No (N)'	Karol Moore (b) (4)	02 Nov 2020 15:47:46

US3312637

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:06:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Nov 2020 15:47:46

US3312637

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:06:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Nov 2020 15:47:46

**US3312637**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:06:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Nov 2020 15:47:46



US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:06:05

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 16:51:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 16:51:45
Data point term sent to Coder	System	02 Nov 2020 15:48:51
User entered 'rosuvastatin'	Karol Moore (b) (4)	02 Nov 2020 15:48:47

**US3312637**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:06:05**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'No (N)'	Karol Moore (b) (4)	02 Nov 2020 15:48:47

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:06:05

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'hypercholesterolemia'	Karol Moore (b) (4)	02 Nov 2020 15:48:47

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:06:05

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '40'	Karol Moore (b) (4)	02 Nov 2020 15:48:47

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:06:05

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'mg (mg)'	Karol Moore (b) (4)	02 Nov 2020 15:48:47

US3312637

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:06:05**

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered empty.	Karol Moore (b) (4)	02 Nov 2020 15:48:47

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:06:05

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'once daily (QD)'	Karol Moore (b) (4)	02 Nov 2020 15:48:47

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:06:05

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered empty.	Karol Moore (b) (4)	02 Nov 2020 15:48:47



**US3312637**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:06:05**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Oral (ORAL)'	Karol Moore (b) (4)	02 Nov 2020 15:48:47

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:06:05

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered empty.	Karol Moore (b) (4)	02 Nov 2020 15:48:47

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:06:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '16 Oct 2020'	Karol Moore (b) (4)	02 Nov 2020 15:48:47

US3312637

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:06:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '0'	Karol Moore (b) (4)	02 Nov 2020 15:48:47

**US3312637**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:06:05**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Yes (Y)'	Karol Moore (b) (4)	02 Nov 2020 15:48:47

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:06:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered empty.	Karol Moore (b) (4)	02 Nov 2020 15:48:47

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:06:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'No (N)'	Karol Moore (b) (4)	02 Nov 2020 15:48:47

**US3312637**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:06:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Nov 2020 15:48:47



US3312637

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:06:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Nov 2020 15:48:47

US3312637

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:06:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Nov 2020 15:48:47

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:06:05

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 17:06:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 17:06:46
Data point term sent to Coder	System	02 Nov 2020 15:49:52
User entered 'famotidine'	Karol Moore (b) (4)	02 Nov 2020 15:49:25

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:06:05

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'No (N)'	Karol Moore (b) (4)	02 Nov 2020 15:49:25

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:06:05

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Gastroesophageal reflux disease'	Karol Moore (b) (4)	02 Nov 2020 15:49:25

US3312637

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:06:05**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '20'	Karol Moore (b) (4)	02 Nov 2020 15:49:25

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:06:05

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'mg (mg)'	Karol Moore (b) (4)	02 Nov 2020 15:49:25

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:06:05

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered empty.	Karol Moore (b) (4)	02 Nov 2020 15:49:25



US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:06:05

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'once daily (QD)'	Karol Moore (b) (4)	02 Nov 2020 15:49:25

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:06:05

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered empty.	Karol Moore (b) (4)	02 Nov 2020 15:49:25

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:06:05

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Oral (ORAL)'	Karol Moore (b) (4)	02 Nov 2020 15:49:25

US3312637

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:06:05**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered empty.	Karol Moore (b) (4)	02 Nov 2020 15:49:25

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:06:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '16 Oct 2020'	Karol Moore (b) (4)	02 Nov 2020 15:49:25

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:06:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '0'	Karol Moore (b) (4)	02 Nov 2020 15:49:25

**US3312637**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:06:05**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Yes (Y)'	Karol Moore (b) (4)	02 Nov 2020 15:49:25

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:06:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered empty.	Karol Moore (b) (4)	02 Nov 2020 15:49:25



US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:06:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'No (N)'	Karol Moore (b) (4)	02 Nov 2020 15:49:25

US3312637

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:06:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Nov 2020 15:49:25

**US3312637**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:06:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Nov 2020 15:49:25

US3312637

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:06:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Nov 2020 15:49:25

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:06:05

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: PRASUGREL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 18:56:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 18:56:20
Data point term sent to Coder	System	06 Nov 2020 18:55:26
User entered 'prasugrel'	(b) (4), (b) (6)	06 Nov 2020 18:55:06

**US3312637**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:06:05**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 18:55:06

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:06:05

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'CORONARY ARTERY DISEASE'	(b) (4), (b) (6)	06 Nov 2020 18:55:06

**US3312637**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:06:05**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '10'	(b) (4), (b) (6)	06 Nov 2020 18:55:06



US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:06:05

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'mg (mg)'	(b) (4), (b) (6)	06 Nov 2020 18:55:06

US3312637

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:06:05**

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 18:55:06

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:06:05

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'once daily (QD)'	(b) (4), (b) (6)	06 Nov 2020 18:55:06

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:06:05

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 18:55:06

**US3312637**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:06:05**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	06 Nov 2020 18:55:06

US3312637

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:06:05**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 18:55:06

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:06:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '16 Oct 2020'	(b) (4), (b) (6)	06 Nov 2020 18:55:06

US3312637

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:06:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '0'	(b) (4), (b) (6)	06 Nov 2020 18:55:06



**US3312637**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:06:05**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Nov 2020 18:55:06

**US3312637**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:06:05**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 18:55:06

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:06:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 18:55:06

**US3312637**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:06:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 18:55:06

US3312637

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:06:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 18:55:06

US3312637

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:06:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Nov 2020 18:55:06

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:06:05

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:26
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: PRASUGREL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 16:56:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 16:56:50
Data point term sent to Coder	System	10 Nov 2020 16:36:15
User entered 'prasugrel'	(b) (4), (b) (6)	10 Nov 2020 16:35:49

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:06:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:26
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User closed query 'Per DM CLR: Prophylaxis = Yes. Please review if this indication should be changed to No as there is an MH recorded (MH#18) that matches this medication. If yes, please update 'Prophylaxis' as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 11:59:13
Query 'Per DM CLR: Prophylaxis = Yes. Please review if this indication should be changed to No as there is an MH recorded (MH#18) that matches this medication. If yes, please update 'Prophylaxis' as appropriate.' answered with 'updated' (Site from DM).	Karol Moore (b) (4)	21 Dec 2020 15:48:10
User entered 'No (N)' reason for change: Data Entry Error	Karol Moore (b) (4)	21 Dec 2020 15:48:06
User opened query 'Per DM CLR: Prophylaxis = Yes. Please review if this indication should be changed to No as there is an MH recorded (MH#18) that matches this medication. If yes, please update 'Prophylaxis' as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 07:03:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 16:35:49



US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:06:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:26
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Coranary artery disease'	(b) (4), (b) (6)	10 Nov 2020 16:35:49

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:06:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:26
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '60'	(b) (4), (b) (6)	10 Nov 2020 16:35:49

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:06:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:26
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'mg (mg)'	(b) (4), (b) (6)	10 Nov 2020 16:35:49

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:06:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:26
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 16:35:49

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:06:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:26
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'once (ONCE)'	(b) (4), (b) (6)	10 Nov 2020 16:35:49

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:06:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:26
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 16:35:49

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:06:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:26
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Nov 2020 16:35:49

**US3312637**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:06:05**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:26
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 16:35:49



**US3312637**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:06:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:26
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '15 Oct 2020'	(b) (4), (b) (6)	10 Nov 2020 16:35:49

**US3312637**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:06:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:26
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '0'	(b) (4), (b) (6)	10 Nov 2020 16:35:49

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:06:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:26
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'No (N)'	(b) (4), (b) (6)	10 Nov 2020 16:35:49

**US3312637**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:06:05**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:26
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '15 Oct 2020'	(b) (4), (b) (6)	10 Nov 2020 16:35:49

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:06:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:26
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'No (N)'	(b) (4), (b) (6)	10 Nov 2020 16:35:49

US3312637

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:06:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:26
User entered empty.	System	10 Nov 2020 16:35:49

US3312637

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:06:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:26
User entered empty.	System	10 Nov 2020 16:35:49

US3312637

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:06:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:26
User entered empty.	System	10 Nov 2020 16:35:49



US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:06:05

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 20:30:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 20:30:46
Data point term sent to Coder	System	10 Nov 2020 20:29:59
User entered 'trazadone'	(b) (4), (b) (6)	10 Nov 2020 20:29:59

US3312637

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:06:05**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'No (N)'	(b) (4), (b) (6)	10 Nov 2020 20:29:59

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:06:05

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'difficulty sleeping'	(b) (4), (b) (6)	10 Nov 2020 20:29:59

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:06:05

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '50'	(b) (4), (b) (6)	10 Nov 2020 20:29:59

US3312637

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:06:05**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'mg (mg)'	(b) (4), (b) (6)	10 Nov 2020 20:29:59

US3312637

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:06:05**

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 20:29:59

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:06:05

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'once daily (QD)'	(b) (4), (b) (6)	10 Nov 2020 20:29:59

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:06:05

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 20:29:59



**US3312637**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:06:05**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Nov 2020 20:29:59

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:06:05

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 20:29:59

**US3312637**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:06:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'un UNK 2017'	(b) (4), (b) (6)	10 Nov 2020 20:29:59

**US3312637**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:06:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '0'	(b) (4), (b) (6)	10 Nov 2020 20:29:59

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:06:05

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 20:29:59

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:06:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 20:29:59

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:06:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 20:30:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Nov 2020 20:30:47
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 20:30:47
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 20:29:59
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 20:29:59

US3312637

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:06:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 20:29:59



US3312637

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:06:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 20:29:59

US3312637

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:06:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Nov 2020 20:29:59

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:06:05

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: DIAZEPINES, OXAZEPINES, THIAZEPINES AND OXEPINES, PRODUCT: QUETIAPINE FUMARATE, PRODUCTSYNONYM: SEROQUEL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 20:31:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 20:31:40
Data point term sent to Coder	System	10 Nov 2020 20:31:03
User entered 'seroquel'	(b) (4), (b) (6)	10 Nov 2020 20:30:40

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:06:05

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'No (N)'	(b) (4), (b) (6)	10 Nov 2020 20:30:40

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:06:05

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'depression'	(b) (4), (b) (6)	10 Nov 2020 20:30:40

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:06:05

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '100'	(b) (4), (b) (6)	10 Nov 2020 20:30:40

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:06:05

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'mg (mg)'	(b) (4), (b) (6)	10 Nov 2020 20:30:40

US3312637

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:06:05**

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 20:30:40



US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:06:05

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'once daily (QD)'	(b) (4), (b) (6)	10 Nov 2020 20:30:40

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:06:05

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 20:30:40

US3312637

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:06:05**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Nov 2020 20:30:40

US3312637

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:06:05**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 20:30:40

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:06:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'un UNK 2001'	(b) (4), (b) (6)	10 Nov 2020 20:30:40

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:06:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '0'	(b) (4), (b) (6)	10 Nov 2020 20:30:40

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:06:05

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 20:30:40

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:06:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 20:30:40



US3312637

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:06:05**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'No (N)'	(b) (4), (b) (6)	10 Nov 2020 20:30:40

US3312637

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:06:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 20:30:40

US3312637

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:06:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 20:30:40

US3312637

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:06:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Nov 2020 20:30:40

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:06:05

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:37
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: HYDROCODONE/ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Jan 2021 12:39:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Jan 2021 12:39:18
Data point term sent to Coder	System	27 Jan 2021 18:12:17
User entered 'hydrocodone 7.5MG/ acetaminophen 325 MG'	(b) (4), (b) (6)	27 Jan 2021 18:11:47

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:06:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:37
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'No (N)'	(b) (4), (b) (6)	27 Jan 2021 18:11:47

**US3312637**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:06:05**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:37
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'umbilical hernia'	(b) (4), (b) (6)	27 Jan 2021 18:11:47

**US3312637**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:06:05**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:37
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '2'	(b) (4), (b) (6)	27 Jan 2021 18:11:47



US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:06:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:37
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	27 Jan 2021 18:11:47

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:06:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:37
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered empty.	(b) (4), (b) (6)	27 Jan 2021 18:11:47

**US3312637**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:06:05**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:37
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'as needed (PRN)'	(b) (4), (b) (6)	27 Jan 2021 18:11:47

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:06:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:37
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered empty.	(b) (4), (b) (6)	27 Jan 2021 18:11:47

**US3312637**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:06:05**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:37
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	27 Jan 2021 18:11:47

**US3312637**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:06:05**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:37
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered empty.	(b) (4), (b) (6)	27 Jan 2021 18:11:47

**US3312637**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:06:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:37
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '30 Dec 2020'	(b) (4), (b) (6)	27 Jan 2021 18:11:47

**US3312637**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:06:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:37
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '0'	(b) (4), (b) (6)	27 Jan 2021 18:11:47



**US3312637**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:06:05**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:37
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'No (N)'	(b) (4), (b) (6)	27 Jan 2021 18:11:47

US3312637

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:06:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:37
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '06 Jan 2021'	(b) (4), (b) (6)	27 Jan 2021 18:11:47

**US3312637**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:06:05**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:37
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:17
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'No (N)'	(b) (4), (b) (6)	27 Jan 2021 18:11:47

US3312637

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:06:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:37
User entered empty.	System	27 Jan 2021 18:11:47

US3312637

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:06:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:37
User entered empty.	System	27 Jan 2021 18:11:47

US3312637

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:06:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:37
User entered empty.	System	27 Jan 2021 18:11:47

US3312637

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:06:05

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:26:16
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:38:27
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Yes (Y)'	Karol Moore (b) (4)	02 Nov 2020 15:55:14

US3312637

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:06:05

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	25 Apr 2021 14:21:53
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 15:12:14
User closed query 'Source log states 15Oct2020. Please verify and update as needed. Thanks ' (Site from CRA).	(b) (4), (b) (6)	24 Apr 2021 15:12:11
Query 'Source log states 15Oct2020. Please verify and update as needed. Thanks ' answered with 'UPDATED PER SOURCE' (Site from CRA).	Karol Moore (b) (4)	23 Apr 2021 23:20:35
Signature has been broken.	Karol Moore (b) (4)	23 Apr 2021 23:20:20
User entered '15 Oct 2020' reason for change: Data Entry Error	Karol Moore (b) (4)	23 Apr 2021 23:20:20
User opened query 'Source log states 15Oct2020. Please verify and update as needed. Thanks ' (Site from CRA).	(b) (4), (b) (6)	22 Apr 2021 15:40:14
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '16 Oct 2020'	Karol Moore (b) (4)	02 Nov 2020 15:55:55



US3312637

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:06:05

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 15:12:14
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'cardiac catheterization with stent'	Karol Moore (b) (4)	02 Nov 2020 15:55:55

US3312637

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:06:05

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 15:12:14
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Adverse Event (AE)'	Karol Moore (b) (4)	02 Nov 2020 15:55:55

US3312637

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 09 Jun 2021 17:06:05**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 15:12:14
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered empty.	Karol Moore (b) (4)	02 Nov 2020 15:55:55

US3312637

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 09 Jun 2021 17:06:05**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:25:24
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 15:12:14
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '30 Dec 2020'	(b) (4), (b) (6)	27 Jan 2021 18:13:03

US3312637

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:06:05

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:25:24
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 15:12:14
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'umbilical hernia repair'	(b) (4), (b) (6)	27 Jan 2021 18:13:03

US3312637

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:06:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:25:24
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 15:12:14
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'Medical History (MH)'	(b) (4), (b) (6)	27 Jan 2021 18:13:03

US3312637

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:06:05

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:25:24
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 15:12:14
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered empty.	(b) (4), (b) (6)	27 Jan 2021 18:13:03

**US3312637**

**Folder: End of Study (1)**

**Form: Dosing Discontinuation**

**Generated On: 09 Jun 2021 17:06:05**

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:00:46
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:58
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '20 Oct 2020' reason for change: Data Entry Error	Karol Moore (b) (4)	15 Dec 2020 22:31:51
User entered '09 Oct 2020'	Karol Moore (b) (4)	15 Dec 2020 21:50:49



US3312637

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:06:05

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:00:46
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:58
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'AE (specify) (ADVERSE EVENT)' reason for change: Data Entry Error	Karol Moore (b) (4)	21 Dec 2020 15:42:23
User entered 'Physician decision (specify) (PHYSICIAN DECISION)'	Karol Moore (b) (4)	15 Dec 2020 21:50:49

US3312637

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:06:05

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:00:46
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:58
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'AE #1' reason for change: Data Entry Error	Karol Moore (b) (4)	21 Dec 2020 15:42:23
User entered 'upcoming cardiac catheterization'	Karol Moore (b) (4)	15 Dec 2020 21:50:49

**US3312637**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:06:05**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:48
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:12:01
User entered 'USA-US300-2020-MRNA-1273-P301000006'	System	21 Oct 2020 18:11:37

**US3312637**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:06:05**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:48
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:12:01
User entered 'Yes (Y)'	System	21 Oct 2020 18:11:37

**US3312637**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:06:05**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:48
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:12:01
User entered 'No (N)'	System	21 Oct 2020 18:11:37

US3312637

Folder: SAE USA-US300-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:05

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:48
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:12:01
User entered 'No (N)'	System	21 Oct 2020 18:11:37

**US3312637**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:06:05**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:48
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:12:01
User entered 'Yes (Y)'	System	21 Oct 2020 18:11:37

**US3312637**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:06:05**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:48
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:12:01
User entered 'No (N)'	System	21 Oct 2020 18:11:37



**US3312637**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:06:05**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:48
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:12:01
User entered 'No (N)'	System	21 Oct 2020 18:11:37

**US3312637**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:06:05**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:48
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:12:01
User entered 'No (N)'	System	21 Oct 2020 18:11:37

US3312637

Folder: SAE USA-US300-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:48
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:12:01
User entered 'Carlos'	System	21 Oct 2020 18:11:37

US3312637

Folder: SAE USA-US300-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:48
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:12:01
User entered 'Fierro'	System	21 Oct 2020 18:11:37

**US3312637**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:06:05**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:48
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:12:01
User entered '16300 College Blvd'	System	21 Oct 2020 18:11:37

**US3312637**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:06:05**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:48
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:12:01
User entered 'Shawnee'	System	21 Oct 2020 18:11:37

**US3312637**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:06:05**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:48
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:12:01
User entered 'KS'	System	21 Oct 2020 18:11:37

**US3312637**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:06:05**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:48
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:12:01
User entered '66219'	System	21 Oct 2020 18:11:37



US3312637

Folder: SAE USA-US300-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:05

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:48
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:52:18
User entered 'US'	System	21 Oct 2020 18:12:10

**US3312637**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:06:05**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	11 Nov 2020 21:52:30
User entered '2'	System	05 Nov 2020 23:25:12
User entered '1'	System	21 Oct 2020 18:12:10

**US3312637**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:06:05**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:48
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:12:01
User entered 'USA-US300-2020-MRNA-1273-P301000006'	System	21 Oct 2020 18:11:37

**US3312637**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:06:05**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:48
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:12:01
User entered 'Yes (Y)'	System	21 Oct 2020 18:11:37

**US3312637**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:06:05**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:48
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:12:01
User entered 'No (N)'	System	21 Oct 2020 18:11:37

**US3312637**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:06:05**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:48
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:12:01
User entered 'No (N)'	System	21 Oct 2020 18:11:37

**US3312637**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:06:05**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:48
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:12:01
User entered 'Yes (Y)'	System	21 Oct 2020 18:11:37

US3312637

Folder: SAE USA-US300-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:48
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:12:01
User entered 'No (N)'	System	21 Oct 2020 18:11:37



**US3312637**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:06:05**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:48
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:12:01
User entered 'No (N)'	System	21 Oct 2020 18:11:37

**US3312637**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:06:05**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:48
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:12:01
User entered 'No (N)'	System	21 Oct 2020 18:11:37

US3312637

Folder: SAE USA-US300-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:48
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:12:01
User entered 'Carlos'	System	21 Oct 2020 18:11:37

US3312637

Folder: SAE USA-US300-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:48
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:12:01
User entered 'Fierro'	System	21 Oct 2020 18:11:37

**US3312637**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:06:05**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:48
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:12:01
User entered '16300 College Blvd'	System	21 Oct 2020 18:11:37

**US3312637**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:06:05**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:48
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:12:01
User entered 'Shawnee'	System	21 Oct 2020 18:11:37

**US3312637**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:06:05**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:48
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:12:01
User entered 'KS'	System	21 Oct 2020 18:11:37

**US3312637**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:06:05**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:48
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:12:01
User entered '66219'	System	21 Oct 2020 18:11:37



**US3312637**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:06:05**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:48
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:52:18
User entered 'US'	System	21 Oct 2020 18:12:10

**US3312637**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:06:05**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	11 Nov 2020 21:52:30
User entered '2'	System	05 Nov 2020 23:25:12
User entered '1'	System	21 Oct 2020 18:12:10

**US3312637**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000006**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 17:06:05**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:48
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '21/Oct/2020 18:12'	System	21 Oct 2020 18:12:10

US3312637

Folder: SAE USA-US300-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:06:05

**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.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:48
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:52:18
User entered 'I'	(b) (4), (b) (6)	21 Oct 2020 18:12:10

**US3312637**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:06:05**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:48
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:12:01
User entered 'USA-US300-2020-MRNA-1273-P301000006'	System	21 Oct 2020 18:11:37

**US3312637**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:06:05**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:48
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:12:01
User entered 'Yes (Y)'	System	21 Oct 2020 18:11:37

**US3312637**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:06:05**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:48
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:12:01
User entered 'No (N)'	System	21 Oct 2020 18:11:37

**US3312637**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:06:05**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:48
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:12:01
User entered 'No (N)'	System	21 Oct 2020 18:11:37



**US3312637**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:06:05**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:48
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:12:01
User entered 'Yes (Y)'	System	21 Oct 2020 18:11:37

US3312637

Folder: SAE USA-US300-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:48
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:12:01
User entered 'No (N)'	System	21 Oct 2020 18:11:37

**US3312637**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:06:05**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:48
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:12:01
User entered 'No (N)'	System	21 Oct 2020 18:11:37

**US3312637**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:06:05**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:48
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:12:01
User entered 'No (N)'	System	21 Oct 2020 18:11:37

US3312637

Folder: SAE USA-US300-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:48
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:12:01
User entered 'Carlos'	System	21 Oct 2020 18:11:37

US3312637

Folder: SAE USA-US300-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:48
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:12:01
User entered 'Fierro'	System	21 Oct 2020 18:11:37

**US3312637**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:06:05**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:48
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:12:01
User entered '16300 College Blvd'	System	21 Oct 2020 18:11:37

**US3312637**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:06:05**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:48
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:12:01
User entered 'Shawnee'	System	21 Oct 2020 18:11:37



**US3312637**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:06:05**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:48
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:12:01
User entered 'KS'	System	21 Oct 2020 18:11:37

**US3312637**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:06:05**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:48
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:12:01
User entered '66219'	System	21 Oct 2020 18:11:37

**US3312637**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:06:05**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:48
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:52:18
User entered 'US'	System	21 Oct 2020 18:12:10

**US3312637**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:06:05**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	11 Nov 2020 21:52:30
User entered '2'	System	05 Nov 2020 23:25:12
User entered '1'	System	21 Oct 2020 18:12:10

**US3312637**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000006**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 17:06:05**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:48
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '05/Nov/2020 18:25'	System	05 Nov 2020 23:25:12

US3312637

Folder: SAE USA-US300-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:06:05

**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.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:48
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:52:18
User entered 'I'	(b) (4), (b) (6)	05 Nov 2020 23:25:12

**US3312637**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:06:05**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:48
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:12:01
User entered 'USA-US300-2020-MRNA-1273-P301000006'	System	21 Oct 2020 18:11:37

**US3312637**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:06:05**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:48
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:12:01
User entered 'Yes (Y)'	System	21 Oct 2020 18:11:37



**US3312637**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:06:05**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:48
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:12:01
User entered 'No (N)'	System	21 Oct 2020 18:11:37

**US3312637**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:06:05**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:48
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:12:01
User entered 'No (N)'	System	21 Oct 2020 18:11:37

**US3312637**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:06:05**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:48
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:12:01
User entered 'Yes (Y)'	System	21 Oct 2020 18:11:37

**US3312637**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:06:05**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:48
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:12:01
User entered 'No (N)'	System	21 Oct 2020 18:11:37

**US3312637**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:06:05**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:48
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:12:01
User entered 'No (N)'	System	21 Oct 2020 18:11:37

**US3312637**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:06:05**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:48
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:12:01
User entered 'No (N)'	System	21 Oct 2020 18:11:37

US3312637

Folder: SAE USA-US300-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:48
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:12:01
User entered 'Carlos'	System	21 Oct 2020 18:11:37

US3312637

Folder: SAE USA-US300-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:48
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:12:01
User entered 'Fierro'	System	21 Oct 2020 18:11:37



**US3312637**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:06:05**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:48
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:12:01
User entered '16300 College Blvd'	System	21 Oct 2020 18:11:37

**US3312637**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:06:05**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:48
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:12:01
User entered 'Shawnee'	System	21 Oct 2020 18:11:37

**US3312637**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:06:05**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:48
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:12:01
User entered 'KS'	System	21 Oct 2020 18:11:37

**US3312637**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:06:05**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:48
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:12:01
User entered '66219'	System	21 Oct 2020 18:11:37

US3312637

Folder: SAE USA-US300-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:05

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:48
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:52:18
User entered 'US'	System	21 Oct 2020 18:12:10

**US3312637**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:06:05**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	11 Nov 2020 21:52:30
User entered '2'	System	05 Nov 2020 23:25:12
User entered '1'	System	21 Oct 2020 18:12:10

**US3312637**

**Folder: SAE USA-US300-2020-MRNA-1273-P301000006**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 17:06:05**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:48
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered '11/Nov/2020 21:52'	System	11 Nov 2020 21:52:30

US3312637

Folder: SAE USA-US300-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:06:05

**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.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:48
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:19:53
User entered 'I'	(b) (4), (b) (6)	11 Nov 2020 21:52:30