

US3312197 (Prod: Johnson County Clin-Trials)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:01:02

All time stamps listed in this document are displayed in GMT

US3312197

Form: Participant Creation

Data signed: (b) (4) 05 Apr 2021 21:14:10

Generated On: 09 Jun 2021 17:01:02

[Participant ID](#)

US3312197

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

US3312197

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 22:06:27

Generated On: 09 Jun 2021 17:01:02

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	20 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3312197

Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 22:06:26

Generated On: 09 Jun 2021 17:01:02

Date of Birth (MMM yyyy)	(b) (6) 1950
Age	69
Age Units	YEARS
Age (Derived)	69
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	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3312197

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 22:06:26

Generated On: 09 Jun 2021 17:01:02

Date of Informed Consent (<i>dd MMM yyyy</i>)	20 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3312197

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 22:06:27

Generated On: 09 Jun 2021 17:01:02

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3312197

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 22:06:27

Generated On: 09 Jun 2021 17:01:02

Were any significant conditions reported?

Yes ☒

No ☐

US3312197

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 15 Feb 2021 22:06:27

Generated On: 09 Jun 2021 17:01:02

Condition	BENIGN PROSTATIC HYPERPLASIA
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)	_____

US3312197

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Feb 2021 22:06:27

Generated On: 09 Jun 2021 17:01:02

Condition	ANXIETY
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)	

US3312197

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 15 Feb 2021 22:06:27

Generated On: 09 Jun 2021 17:01:02

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

US3312197

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 15 Feb 2021 22:06:27

Generated On: 09 Jun 2021 17:01:02

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

US3312197

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 15 Feb 2021 22:06:27

Generated On: 09 Jun 2021 17:01:02

Condition	ATRIL FIBRILLATION
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)	

US3312197

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 15 Feb 2021 22:06:27

Generated On: 09 Jun 2021 17:01:02

Condition	GASTROESOPHAGEAL REFLUX 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)	

US3312197

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 15 Feb 2021 22:06:27

Generated On: 09 Jun 2021 17:01:02

Condition	SEASONAL ALLERGIES
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)	

US3312197

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 15 Feb 2021 22:06:27

Generated On: 09 Jun 2021 17:01:02

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

US3312197

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 15 Feb 2021 22:06:27

Generated On: 09 Jun 2021 17:01:02

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

US3312197

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 15 Feb 2021 22:06:27

Generated On: 09 Jun 2021 17:01:02

Condition	BILATERAL CARPAL TUNNEL
Start date (dd MMM yyyy)	UN UNK 2007
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 2007
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2007
Start Year (derived)	2007
Stop Month and Year (derived)	JAN 2007
Stop Year (derived)	2007

US3312197

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 15 Feb 2021 22:06:27

Generated On: 09 Jun 2021 17:01:02

Condition	BILATERAL CARPAL TUNNEL REPAIR
Start date (dd MMM yyyy)	UN UNK 2007
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 2007
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2007
Start Year (derived)	2007
Stop Month and Year (derived)	JAN 2007
Stop Year (derived)	2007

US3312197

Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 15 Feb 2021 22:06:27

Generated On: 09 Jun 2021 17:01:02

Condition	SPINAL STENOSIS
Start date (dd MMM yyyy)	UN UNK 1990
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 2012
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	JAN 2012
Stop Year (derived)	2012

US3312197

Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 15 Feb 2021 22:06:27

Generated On: 09 Jun 2021 17:01:02

Condition	SPINAL LAMINECTOMY
Start date (dd MMM yyyy)	UN UNK 2012
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 2012
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	JAN 2012
Stop Year (derived)	2012

US3312197

Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 15 Feb 2021 22:06:27

Generated On: 09 Jun 2021 17:01:02

Condition	RIGHT ROTATOR CUFF TEAR
Start date (dd MMM yyyy)	UN MAR 2020
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 MAR 2020
Stop date completely unknown	False
Start Month and Year (derived)	MAR 2020
Start Year (derived)	2020
Stop Month and Year (derived)	MAR 2020
Stop Year (derived)	2020

US3312197

Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 15 Feb 2021 22:06:27

Generated On: 09 Jun 2021 17:01:02

Condition	RIGHT ROTATOR CUFF REPAIR
Start date (dd MMM yyyy)	UN MAY 2020
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 MAY 2020
Stop date completely unknown	False
Start Month and Year (derived)	MAY 2020
Start Year (derived)	2020
Stop Month and Year (derived)	MAY 2020
Stop Year (derived)	2020

US3312197

Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 15 Feb 2021 22:06:27

Generated On: 09 Jun 2021 17:01:02

Condition	GYNECOMASTIA
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)	

US3312197

Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 15 Feb 2021 22:06:27

Generated On: 09 Jun 2021 17:01:02

Condition	OSTEOARTHRITIS OF NECK AND SHOULDERS
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)	

US3312197

Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 15 Feb 2021 22:06:27

Generated On: 09 Jun 2021 17:01:02

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

US3312197

Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 15 Feb 2021 22:06:27

Generated On: 09 Jun 2021 17:01:02

Condition	LEFT CERVICAL RADICULOPATHY
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)	

US3312197

Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) 15 Feb 2021 22:06:27

Generated On: 09 Jun 2021 17:01:02

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

US3312197

Folder: Screening

Form: Medical History (21)

Data signed: (b) (4) 15 Feb 2021 22:06:27

Generated On: 09 Jun 2021 17:01:02

Condition	ANOSMIA
Start date (dd MMM yyyy)	UN UNK 1969
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 1969
Start Year (derived)	1969
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3312197

Folder: Screening

Form: Medical History (22)

Data signed: (b) (4) 15 Feb 2021 22:06:27

Generated On: 09 Jun 2021 17:01:02

Condition	SLEEP APNEA
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)	

US3312197

Folder: Screening

Form: Medical History (23)

Data signed: (b) (4) 15 Feb 2021 22:06:27

Generated On: 09 Jun 2021 17:01:02

Condition	DEPRESSION
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)	_____

US3312197

Folder: Screening

Form: Medical History (24)

Data signed: (b) (4) 15 Feb 2021 22:06:27

Generated On: 09 Jun 2021 17:01:02

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

US3312197

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 22:06:27

Generated On: 09 Jun 2021 17:01:02

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	20 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	13:57 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 13:57
Height (<i>xxx.x</i>)	66 in
Weight (<i>xxx.x</i>)	249 lb
BMI (<i>xxx.x</i>)	40.27368 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3312197

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 22:06:27

Generated On: 09 Jun 2021 17:01:02

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 AUG 2020

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

US3312197

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 22:06:27

Generated On: 09 Jun 2021 17:01:02

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

US3312197

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 22:06:27

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

US3312197

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 22:06:27

Generated On: 09 Jun 2021 17:01:02

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

Visit date (dd MMM yyyy)	20 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT1
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US3312197

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 22:06:27

Generated On: 09 Jun 2021 17:01:02

What was the date of randomization? (dd MMM yyyy) 20 AUG 2020

What was the participant's randomization number? 187332

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 ☒

US3312197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 22:06:27

Generated On: 09 Jun 2021 17:01:02

Height	ND - Not Done
Weight	ND - Not Done

US3312197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 22:06:27

Generated On: 09 Jun 2021 17:01:02

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)	20 AUG 2020
Time of assessment (00:00-23:59)	13:57 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 13:57
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3312197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 22:06:27

Generated On: 09 Jun 2021 17:01:02

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	20 AUG 2020
Time of assessment (00:00-23:59)	15:20 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 15:20
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3312197

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 22:06:27

Generated On: 09 Jun 2021 17:01:02

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.

US3312197

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 22:06:27

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Was study treatment given? Yes ☒ No ☐

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 20 AUG 2020

What was the treatment time? (00:00-23:59) 14:49 (24 HR)

Treatment Date and Time (derived) 20 AUG 2020 14:49

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

US3312197

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 22:06:27

Generated On: 09 Jun 2021 17:01:02

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

20 AUG 2020

Collection time (00:00-23:59)

14:14 (24 HR)

Collection date and time (derived)

20 AUG 2020 14:14

US3312197

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 22:06:27

Generated On: 09 Jun 2021 17:01:02

Collection date (dd MMM yyyy)			20 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:12	20 AUG 2020 14:12
Nasopharyngeal Swab 2	No		

US3312197

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:06:27

Generated On: 09 Jun 2021 17:01:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 AUG 2020 15:17

PC Open Date & Time

20 AUG 2020 15:09

PC Close Date & Time

20 AUG 2020 17:39

US3312197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

97.8 °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	20 AUG 2020 18:35
PC Open Date & Time	20 AUG 2020 18:34
PC Close Date & Time	21 AUG 2020 11:59

US3312197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 AUG 2020 14:51

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3312197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:01:02

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

22 AUG 2020 18:50

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3312197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:01:02

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

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 AUG 2020 18:35

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3312197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 21:01

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3312197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 AUG 2020 18:37

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3312197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

DAY 7

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 AUG 2020 18:46

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3312197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 AUG 2020 15:17

PC Open Date & Time

20 AUG 2020 15:09

PC Close Date & Time

20 AUG 2020 17:39

US3312197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:01:02

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

20 AUG 2020 18:35

PC Open Date & Time

20 AUG 2020 18:34

PC Close Date & Time

21 AUG 2020 11:59

US3312197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:01:02

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

21 AUG 2020 14:53

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3312197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:01:02

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

22 AUG 2020 18:50

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3312197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:01:02

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

23 AUG 2020 18:36

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3312197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:01:02

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

24 AUG 2020 21:01

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3312197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:01:02

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

25 AUG 2020 18:37

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3312197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:01:02

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

26 AUG 2020 18:47

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:01:02

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 ☐

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:01:02

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

No ☒

Yes ☐

PC Time stamp	20 AUG 2020 15:25
PC Open Date & Time	20 AUG 2020 15:09
PC Close Date & Time	20 AUG 2020 17:39

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:01:02

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 ☐

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:01:02

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

No ☒

Yes ☐

PC Time stamp	20 AUG 2020 18:36
PC Open Date & Time	20 AUG 2020 18:34
PC Close Date & Time	21 AUG 2020 11:59

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:01:02

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 ☒

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:01:02

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 14:53
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

67 of 3104

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:01:02

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 18:51
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

69 of 3104

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:01:02

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 18:36
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:01:02

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

71 of 3104

EAB) (1725)

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:01:02

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 21:02
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:01:02

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 ☐

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:01:02

		Yes <input type="checkbox"/>
PC Time stamp	25 AUG 2020 18:38	
PC Open Date & Time	25 AUG 2020 12:00	
PC Close Date & Time	26 AUG 2020 11:59	

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

75 of 3104

EAB) (1725)

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:01:02

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 18:47
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3312197

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:06:26

Generated On: 09 Jun 2021 17:01:02

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312197

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:06:26

Generated On: 09 Jun 2021 17:01:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312197

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:06:16

Generated On: 09 Jun 2021 17:01:02

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312197

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:06:16

Generated On: 09 Jun 2021 17:01:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312197

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:06:26

Generated On: 09 Jun 2021 17:01:02

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312197

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:06:16

Generated On: 09 Jun 2021 17:01:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312197

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 22:06:27

Generated On: 09 Jun 2021 17:01:02

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3312197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 22:06:27

Generated On: 09 Jun 2021 17:01:02

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)	17 SEP 2020
Time of assessment (00:00-23:59)	10:01 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 10:01
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG

US3312197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 22:06:27

Generated On: 09 Jun 2021 17:01:02

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

US3312197

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 22:06:27

Generated On: 09 Jun 2021 17:01:02

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 SEP 2020

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

US3312197

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 22:06:27

Generated On: 09 Jun 2021 17:01:02

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 EXACERBATION OF LEFT CERVICAL RADICULOPATHY

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? _____

US3312197

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 22:06:27

Generated On: 09 Jun 2021 17:01:02

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

17 SEP 2020

Collection time (00:00-23:59)

11:01 (24 HR)

Collection date and time (derived)

17 SEP 2020 11:01

US3312197

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 22:06:27

Generated On: 09 Jun 2021 17:01:02

Collection date (dd MMM yyyy)			17 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:54	17 SEP 2020 10:54
Nasopharyngeal Swab 2	No		

US3312197

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:06:27

Generated On: 09 Jun 2021 17:01:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312197

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:06:26

Generated On: 09 Jun 2021 17:01:02

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312197

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:06:26

Generated On: 09 Jun 2021 17:01:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312197

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:06:26

Generated On: 09 Jun 2021 17:01:02

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312197

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:06:26

Generated On: 09 Jun 2021 17:01:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312197

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:06:26

Generated On: 09 Jun 2021 17:01:02

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312197

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:06:26

Generated On: 09 Jun 2021 17:01:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312197

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 22:06:27

Generated On: 09 Jun 2021 17:01:02

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3312197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 22:06:27

Generated On: 09 Jun 2021 17:01:02

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 OCT 2020
Time of assessment (00:00-23:59)	08:33 (24 HR)
Vital Signs Date and Time (derived)	12 OCT 2020 08:33
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)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	61 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3312197

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 22:06:27

Generated On: 09 Jun 2021 17:01:02

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 OCT 2020

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

US3312197

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 22:06:27

Generated On: 09 Jun 2021 17:01:02

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

12 OCT 2020

Collection time (00:00-23:59)

09:03 (24 HR)

Collection date and time (derived)

12 OCT 2020 09:03

US3312197

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:06:27

Generated On: 09 Jun 2021 17:01:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 OCT 2020 12:30:19
Patient Cloud Open Date & Time	20 OCT 2020 00:01
Patient Cloud Close Date & Time	24 OCT 2020 23:59

US3312197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

27 OCT 2020 10:37:29

Patient Cloud Open Date & Time

27 OCT 2020 00:01

Patient Cloud Close Date & Time

31 OCT 2020 23:59

US3312197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 NOV 2020 16:20:32
Patient Cloud Open Date & Time	03 NOV 2020 00:01
Patient Cloud Close Date & Time	07 NOV 2020 23:59

US3312197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 NOV 2020 08:38:31

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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 type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	False
Chills	False
Cough	True
Shortness of breath	True
Difficulty breathing	False
Fatigue	True
Muscle aches	False
Body aches	False
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	True
Congestion	True
Runny nose	True
Nausea	False
Vomiting	False
Diarrhea	True
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	23 NOV 2020 17:38:32
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

30 NOV 2020 12:47:23

Patient Cloud Open Date & Time

28 NOV 2020 00:01

Patient Cloud Close Date & Time

02 DEC 2020 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

05 DEC 2020 07:31:57

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

14 DEC 2020 12:23:26

Patient Cloud Open Date & Time

12 DEC 2020 00:01

Patient Cloud Close Date & Time

16 DEC 2020 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 DEC 2020 12:50:09

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

26 DEC 2020 01:21:28

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	02 JAN 2021 10:03:22
Patient Cloud Open Date & Time	02 JAN 2021 00:01
Patient Cloud Close Date & Time	06 JAN 2021 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

11 JAN 2021 12:39:59

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

16 JAN 2021 07:59:19

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 JAN 2021 12:09:36

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	31 JAN 2021 12:48:38
Patient Cloud Open Date & Time	30 JAN 2021 00:01
Patient Cloud Close Date & Time	03 FEB 2021 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

06 FEB 2021 07:36:03

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 FEB 2021 18:31:25
Patient Cloud Open Date & Time	13 FEB 2021 00:01
Patient Cloud Close Date & Time	17 FEB 2021 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

20 FEB 2021 11:57:45

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

27 FEB 2021 17:09:23

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

06 MAR 2021 11:46:38

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

14 MAR 2021 19:37:36

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

20 MAR 2021 11:09:53

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

27 MAR 2021 07:55:32

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

03 APR 2021 09:52:58

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	10 APR 2021 17:25:34
Patient Cloud Open Date & Time	10 APR 2021 00:01
Patient Cloud Close Date & Time	14 APR 2021 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 APR 2021 08:15:14

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 APR 2021 06:54:27

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 MAY 2021 11:34:57

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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"/>

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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 <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"/>

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

15 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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"/>

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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 <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"/>

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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 ☐

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

12 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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 ☐

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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 ☐

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

26 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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="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"/>

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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 ☐

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	17 JUL 2021 00:01
Patient Cloud Close Date & Time	21 JUL 2021 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	24 JUL 2021 00:01
Patient Cloud Close Date & Time	28 JUL 2021 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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"/>

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	14 AUG 2021 00:01
Patient Cloud Close Date & Time	18 AUG 2021 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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 ☐

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	21 AUG 2021 00:01
Patient Cloud Close Date & Time	25 AUG 2021 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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 ☐

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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 ☐

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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 <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"/>

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	11 SEP 2021 00:01
Patient Cloud Close Date & Time	15 SEP 2021 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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 ☐

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	18 SEP 2021 00:01
Patient Cloud Close Date & Time	22 SEP 2021 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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"/>

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	25 SEP 2021 00:01
Patient Cloud Close Date & Time	29 SEP 2021 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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"/>

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	02 OCT 2021 00:01
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Patient Cloud Close Date & Time	06 OCT 2021 23:59
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US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	09 OCT 2021 00:01
Patient Cloud Close Date & Time	13 OCT 2021 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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"/>

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	16 OCT 2021 00:01
Patient Cloud Close Date & Time	20 OCT 2021 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

23 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

DAY 453

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

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

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

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

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

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

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

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

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	13 NOV 2021 00:01
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Patient Cloud Close Date & Time	17 NOV 2021 23:59
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US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	20 NOV 2021 00:01
Patient Cloud Close Date & Time	24 NOV 2021 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

[Patient Cloud Open Date & Time](#)

27 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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 ☐

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	04 DEC 2021 00:01
Patient Cloud Close Date & Time	08 DEC 2021 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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 ☐

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	11 DEC 2021 00:01
Patient Cloud Close Date & Time	15 DEC 2021 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	18 DEC 2021 00:01
Patient Cloud Close Date & Time	22 DEC 2021 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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"/>

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	25 DEC 2021 00:01
Patient Cloud Close Date & Time	29 DEC 2021 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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 <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"/>

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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 ☐

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

15 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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 ☐

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	22 JAN 2022 00:01
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Patient Cloud Close Date & Time	26 JAN 2022 23:59
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US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

05 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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"/>

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

12 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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 ☐

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

DAY 558

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

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

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

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

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

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

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

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

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

26 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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 ☐

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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 ☐

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

12 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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 ☐

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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 ☐

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	26 MAR 2022 00:01
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Patient Cloud Close Date & Time	30 MAR 2022 23:59
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US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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 ☐

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

02 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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"/>

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	16 APR 2022 00:01
Patient Cloud Close Date & Time	20 APR 2022 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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"/>

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

Date and time of submission	
Patient Cloud Open Date & Time	23 APR 2022 00:01
Patient Cloud Close Date & Time	27 APR 2022 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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 ☐

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

11 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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"/>

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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 ☐

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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"/>

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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"/>

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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="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"/>

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	16 JUL 2022 00:01
Patient Cloud Close Date & Time	20 JUL 2022 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

DAY 705

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

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

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

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

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

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

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

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

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

23 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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 <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"/>

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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"/>

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

06 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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"/>

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

13 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2022 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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="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"/>

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

20 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

[Patient Cloud Open Date & Time](#)

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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 ☐

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

03 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

[Patient Cloud Open Date & Time](#)

10 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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 ☐

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

17 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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"/>

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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 ☐

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	01 OCT 2022 00:01
Patient Cloud Close Date & Time	05 OCT 2022 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	08 OCT 2022 00:01
Patient Cloud Close Date & Time	12 OCT 2022 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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 <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"/>

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	15 OCT 2022 00:01
Patient Cloud Close Date & Time	19 OCT 2022 23:59

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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"/>

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2022 23:59

US3312197

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:01:02

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 17:11:30

US3312197

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 21:14:40

Generated On: 09 Jun 2021 17:01:02

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 12 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3312197

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:14:40

Generated On: 09 Jun 2021 17:01:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312197

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 21:14:40

Generated On: 09 Jun 2021 17:01:02

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312197

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:14:40

Generated On: 09 Jun 2021 17:01:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312197

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 21:14:40

Generated On: 09 Jun 2021 17:01:02

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312197

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:14:40

Generated On: 09 Jun 2021 17:01:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312197

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 21:14:40

Generated On: 09 Jun 2021 17:01:02

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312197

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:14:40

Generated On: 09 Jun 2021 17:01:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312197

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 21:14:40

Generated On: 09 Jun 2021 17:01:02

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

Visit date (dd MMM yyyy)	02 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
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US3312197

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 21:14:40

Generated On: 09 Jun 2021 17:01:02

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) _____

US3312197

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 21:14:40

Generated On: 09 Jun 2021 17:01:02

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.

US3312197

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 21:14:40

Generated On: 09 Jun 2021 17:01:02

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

02 MAR 2021

Collection time (00:00-23:59)

13:42 (24 HR)

Collection date and time (derived)

02 MAR 2021 13:42

US3312197

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:14:40

Generated On: 09 Jun 2021 17:01:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312197

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 22 Apr 2021 20:40:07

Generated On: 09 Jun 2021 17:01:02

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312197

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 20:40:07

Generated On: 09 Jun 2021 17:01:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312197

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:02

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

US3312197

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:02

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 05 Apr 2021 21:14:12

Generated On: 09 Jun 2021 17:01:02

Date of Contact	24 NOV 2020
Time of Contact	11:22
Date and Time of Contact (derived)	24 NOV 2020 11:22
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 05 Apr 2021 21:14:12

Generated On: 09 Jun 2021 17:01:02

Symptom Day

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

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 05 Apr 2021 21:14:12

Generated On: 09 Jun 2021 17:01:02

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	22 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 05 Apr 2021 21:14:12

Generated On: 09 Jun 2021 17:01:02

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

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 05 Apr 2021 21:14:12

Generated On: 09 Jun 2021 17:01:02

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

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 05 Apr 2021 21:14:12

Generated On: 09 Jun 2021 17:01:02

Symptom Day

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

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 05 Apr 2021 21:14:12

Generated On: 09 Jun 2021 17:01:02

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	23 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

308 of 3104

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 05 Apr 2021 21:14:12

Generated On: 09 Jun 2021 17:01:02

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

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 05 Apr 2021 21:14:12

Generated On: 09 Jun 2021 17:01:02

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

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 05 Apr 2021 21:14:12

Generated On: 09 Jun 2021 17:01:02

Symptom Day

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

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 05 Apr 2021 21:14:12

Generated On: 09 Jun 2021 17:01:02

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	24 NOV 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	97.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 05 Apr 2021 21:14:12

Generated On: 09 Jun 2021 17:01:02

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

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 05 Apr 2021 21:14:12

Generated On: 09 Jun 2021 17:01:02

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

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 05 Apr 2021 21:14:12

Generated On: 09 Jun 2021 17:01:02

Symptom Day

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

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 05 Apr 2021 21:14:12

Generated On: 09 Jun 2021 17:01:02

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	25 NOV 2020	
Assessment Not Done	False	
O2 Saturation	91 %	
O2 Saturation Units	%	
Temperature	98.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 05 Apr 2021 21:14:12

Generated On: 09 Jun 2021 17:01:02

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

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 05 Apr 2021 21:14:12

Generated On: 09 Jun 2021 17:01:02

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

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 05 Apr 2021 21:14:12

Generated On: 09 Jun 2021 17:01:02

Symptom Day

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

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 05 Apr 2021 21:14:12

Generated On: 09 Jun 2021 17:01:02

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	26 NOV 2020	
Assessment Not Done	False	
O2 Saturation	92 %	
O2 Saturation Units	%	
Temperature	98.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 05 Apr 2021 21:14:12

Generated On: 09 Jun 2021 17:01:02

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

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 05 Apr 2021 21:14:12

Generated On: 09 Jun 2021 17:01:02

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

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 05 Apr 2021 21:14:12

Generated On: 09 Jun 2021 17:01:02

Symptom Day

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

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 05 Apr 2021 21:14:12

Generated On: 09 Jun 2021 17:01:02

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	27 NOV 2020	
Assessment Not Done	False	
O2 Saturation	93 %	
O2 Saturation Units	%	
Temperature	97.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 05 Apr 2021 21:14:12

Generated On: 09 Jun 2021 17:01:02

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

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 05 Apr 2021 21:14:12

Generated On: 09 Jun 2021 17:01:02

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

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 05 Apr 2021 21:14:12

Generated On: 09 Jun 2021 17:01:02

Symptom Day

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

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 05 Apr 2021 21:14:12

Generated On: 09 Jun 2021 17:01:02

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	28 NOV 2020	
Assessment Not Done	False	
O2 Saturation	74 %	
O2 Saturation Units	%	
Temperature	97.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 05 Apr 2021 21:14:12

Generated On: 09 Jun 2021 17:01:02

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

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 05 Apr 2021 21:14:12

Generated On: 09 Jun 2021 17:01:02

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

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 05 Apr 2021 21:14:12

Generated On: 09 Jun 2021 17:01:02

Symptom Day

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

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 05 Apr 2021 21:14:12

Generated On: 09 Jun 2021 17:01:02

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	29 NOV 2020	
Assessment Not Done	False	
O2 Saturation	93 %	
O2 Saturation Units	%	
Temperature	97.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 05 Apr 2021 21:14:12

Generated On: 09 Jun 2021 17:01:02

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

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 05 Apr 2021 21:14:12

Generated On: 09 Jun 2021 17:01:02

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

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 05 Apr 2021 21:14:12

Generated On: 09 Jun 2021 17:01:02

Date of Visit 24 NOV 2020

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

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

Date of Test 24 NOV 2020

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

Other, specify

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

If yes, provide lab information below

Lab/ Institution Test Performed

CLIA Certified? Yes ☐ No ☐

COVID-19 Positive (CSA Programming Field Only) 0

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 08 Apr 2021 15:18:45

Generated On: 09 Jun 2021 17:01:02

Did the subject have Respiratory Rates ≥ 30 per Minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

Did the subject have Heart Rate ≥ 125 beats per minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____

Did the subject have Oxygen Saturation of SpO₂ $\leq 93\%$ on room air at sea level? Yes ☒ No ☐

If Yes, provide:

Start Date 25 NOV 2020

End Date 29 NOV 2020

Oxygen Saturation 93 %

Did the subject have PaO₂/FIO₂ Ratio < 300 mm Hg? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date _____

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

Start Date _____

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EAB) (1725)

336 of 3104

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 08 Apr 2021 15:18:45

Generated On: 09 Jun 2021 17:01:02

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

Ventilator Support:

High-Flow Oxygen? Yes ☐
No ☐

Start Date

End Date

Non-Invasive Ventilation? Yes ☐
No ☐

Start Date

End Date

Mechanical Ventilation? Yes ☐
No ☐

Start Date

End Date

ECMO? Yes ☐
No ☐

Start Date

End Date

Evidence of Shock:

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

Start Date

24 NOV 2020

End Date

24 NOV 2020

Evidence of Shock Requires Vasopressors Yes ☐
No ☒

Start Date

End Date

Acute Renal Dysfunction? Yes ☐
No ☒

Start Date

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 08 Apr 2021 15:18:45

Generated On: 09 Jun 2021 17:01:02

Hepatic Dysfunction? Yes ☐
No ☒

Start Date

Neurologic Dysfunction? Yes ☐
No ☒

Start Date

Evidence of Pneumonia:

Clinical Evidence Yes ☐
No ☒

Date of Assessment

Radiographical Evidence Yes ☐
No ☒

Date of Assessment

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

Start Date

End Date

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 05 Apr 2021 21:14:12

Generated On: 09 Jun 2021 17:01:02

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3312197

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 05 Apr 2021 21:14:13

Generated On: 09 Jun 2021 17:01:02

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	26 NOV 2020
Day 5	Yes	28 NOV 2020
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3312197

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 21:14:13

Generated On: 09 Jun 2021 17:01:02

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

Visit date (dd MMM yyyy)	24 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	SICKD1
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US3312197

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 21:14:13

Generated On: 09 Jun 2021 17:01:02

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	24 NOV 2020
Time of assessment (00:00-23:59)	14:03 (24 HR)
Vital Signs Date and Time (derived)	24 NOV 2020 14:03
Height (xxx.x)	66 in
Weight (xxx.x)	247.4 lb
Temperature (xxx.x)	97.7 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)	22 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	58 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3312197

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 21:14:13

Generated On: 09 Jun 2021 17:01:02

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 NOV 2020

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

US3312197

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 05 Apr 2021 21:14:13

Generated On: 09 Jun 2021 17:01:02

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

24 NOV 2020

US3312197

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 21:14:12

Generated On: 09 Jun 2021 17:01:02

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy)

Was visit performed at the participant's home or at the clinic? Home ☐
Clinic ☐

Folder OID SICKD28

US3312197

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 21:14:12

Generated On: 09 Jun 2021 17:01:02

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) _____

US3312197

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 21:14:12

Generated On: 09 Jun 2021 17:01:02

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.

US3312197

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 05 Apr 2021 21:14:12

Generated On: 09 Jun 2021 17:01:02

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☐

No ☒

NA (COVID-19 Negative) ☐

Date of Collection

US3312197

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

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 21:14:40

Generated On: 09 Jun 2021 17:01:02

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

Visit date (dd MMM yyyy)	12 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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US3312197

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

Form: Unblinding

Data signed: (b) (4) 05 Apr 2021 21:14:40

Generated On: 09 Jun 2021 17:01:02

Date of updated informed consent (<i>dd MMM yyyy</i>)	12 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>)	12 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

US3312197

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 05 Apr 2021 21:14:40

Generated On: 09 Jun 2021 17:01:02

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

US3312197

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Apr 2021 21:14:40

Generated On: 09 Jun 2021 17:01:02

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)	12 JAN 2021
Time of assessment (00:00-23:59)	13:26 (24 HR)
Vital Signs Date and Time (derived)	12 JAN 2021 13:26
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3312197

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Apr 2021 21:14:40

Generated On: 09 Jun 2021 17:01:02

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)	12 JAN 2021
Time of assessment (00:00-23:59)	14:55 (24 HR)
Vital Signs Date and Time (derived)	12 JAN 2021 14:55
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)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG

US3312197

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

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 21:14:40

Generated On: 09 Jun 2021 17:01:02

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 JAN 2021

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

US3312197

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

Form: Exposure

Data signed: (b) (4) 05 Apr 2021 21:14:40

Generated On: 09 Jun 2021 17:01:02

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) 12 JAN 2021

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

Treatment Date and Time (derived) 12 JAN 2021 14:23

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

US3312197

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 21:14:40

Generated On: 09 Jun 2021 17:01:02

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

Collection date (dd MMM yyyy)	12 JAN 2021
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Collection time (00:00-23:59)	12:35 (24 HR)
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Collection date and time (derived)	12 JAN 2021 12:35
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US3312197

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 05 Apr 2021 21:14:40

Generated On: 09 Jun 2021 17:01:02

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	12 JAN 2021
Collection time (00:00 - 23:59)	12:34
Collection Date and Time (derived)	12 JAN 2021 12:34

US3312197

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

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:14:40

Generated On: 09 Jun 2021 17:01:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312197

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 21:14:40

Generated On: 09 Jun 2021 17:01:02

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312197

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:14:40

Generated On: 09 Jun 2021 17:01:02

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

US3312197

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 21:14:39

Generated On: 09 Jun 2021 17:01:02

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	09 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3312197

Folder: OL-D29 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 21:14:40

Generated On: 09 Jun 2021 17:01:02

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	09 FEB 2021
Time of assessment (<i>00:00-23:59</i>)	12:32 (24 HR)
Vital Signs Date and Time (derived)	09 FEB 2021 12:32
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>)	70 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	60 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3312197

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 21:14:13

Generated On: 09 Jun 2021 17:01:02

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

09 FEB 2021

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

US3312197

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 21:14:13

Generated On: 09 Jun 2021 17:01:02

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

09 FEB 2021

Collection time (00:00-23:59)

12:45 (24 HR)

Collection date and time (derived)

09 FEB 2021 12:45

US3312197

Folder: **Unscheduled 20 Aug 2020**

Form: **Unscheduled Visit Assessment**

Data signed: (b) (4) 05 Apr 2021 21:14:40

Generated On: 09 Jun 2021 17:01:02

Visit Date	20 AUG 2020
Please check all assessments that apply for this visit	
Physical Exam	False
Vital Signs	True
Immunogenicity Assessment	False
Pregnancy Test	False

US3312197

Folder: Unscheduled 20 Aug 2020

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 21:14:40

Generated On: 09 Jun 2021 17:01:02

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	20 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	15:25 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 15:25
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	69 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3312197

Folder: **Unscheduled 24 Nov 2020**

Form: **Unscheduled Visit Assessment**

Data signed: (b) (4) 05 Apr 2021 21:14:40

Generated On: 09 Jun 2021 17:01:02

Visit Date	24 NOV 2020
Please check all assessments that apply for this visit	
Physical Exam	False
Vital Signs	True
Immunogenicity Assessment	False
Pregnancy Test	False

US3312197

Folder: Unscheduled 24 Nov 2020

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 21:14:40

Generated On: 09 Jun 2021 17:01:02

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	24 NOV 2020
Time of assessment (00:00-23:59)	14:09 (24 HR)
Vital Signs Date and Time (derived)	24 NOV 2020 14:09
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)	20 breaths/min
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)	

US3312197

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Mar 2021 15:50:39

Generated On: 09 Jun 2021 17:01:02

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3312197

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 22 Apr 2021 20:40:06

Generated On: 09 Jun 2021 17:01:02

AEID

Adverse event

ANXIETY EXACERBATION

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

25 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

25 AUG 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

370 of 3104

EAB) (1725)

US3312197

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 22 Apr 2021 20:40:06

Generated On: 09 Jun 2021 17:01:02

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

US3312197

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 22 Apr 2021 20:40:06

Generated On: 09 Jun 2021 17:01:02

AEID

Adverse event

EXACERBATION OF LEFT
CERVICAL RADICULOPATHY

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

06 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

09 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

PRODUCTION RELEASE (v12.003

372 of 3104

EAB) (1725)

US3312197

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 22 Apr 2021 20:40:06

Generated On: 09 Jun 2021 17:01:02

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	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3312197

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 22 Apr 2021 20:40:06

Generated On: 09 Jun 2021 17:01:02

AEID	USA-US300-2020-MRNA-1273-P30 1000015
Adverse event	PNEUMONIA
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)	22 NOV 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)	09 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	28 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	01 DEC 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

374 of 3104

US3312197

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 22 Apr 2021 20:40:06

Generated On: 09 Jun 2021 17:01:02

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

US3312197

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 22 Apr 2021 20:40:06

Generated On: 09 Jun 2021 17:01:02

DAY 1 ILLNESS VISIT WAS ON
24NOV2020 FOR MODERATE
SOB, DIFFICULTY BREATHING,
COUGH, FATIGUE, H/A, NASAL
CONGESTION, RUNNY NOSE,
DIARRHEA, SORE THROAT,
AND MILD NAUSEA ONSET
22NOV2020.AUGMENTIN FOR
COVID-NEGATIVE PNEUMONIA
PRESCRIBED AT URGENT CARE
VISIT 24NOV2020.PREVIOUSLY
UNREPORTED H/O ANOSMIA
SINCE 1969 AND SLEEP APNEA
SINCE 1990 WERE
REVEALED.ON 28NOV2020 SUBJ
WENT TO ER FOR WORSENING
SOB; ADMISSION FOR
PNEUMONIA WITH O2
REQUIREMENT, STARTED ON
O2 AND IV ANTIBIOTICS.ON
29NOV2020 O2SAT WAS 95% ON
1L O2. ON 30NOV2020 SUBJECT
HAD NEGATIVE COVID TEST
RESULT IN HOSPITAL, HAD
MARKEDLY IMPROVED
SYMPTOMS, HAD 92% SAT ON
ROOM AIR, AND SOUNDED
GOOD ON PHONE
CALL.EXPECTED DISCHARGE
DATE 01DEC2020F/U BASED ON
MED RECS REVIEW AND PHONE
CALL WITH SUBJ 07DEC2020.
HOSPITAL DISCHARGE
01DEC2020 WITH O2 SATS 94%
ON RA, NORMAL VITALS,

US3312197

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 22 Apr 2021 20:40:06

Generated On: 09 Jun 2021 17:01:02

MARKEDLY IMPROVED
SYMPTOMS, AND CLEAR LUNG
SOUNDS BILATERALLY AFTER
TREATMENT FOR
COVID-NEGATIVE PNEUMONIA
WITHOUT EVIDENCE OF CHF,
AFIB, NEW HEART
ABNORMALITY, OR CLOTTING
PER PHYSICAL EXAM, EKG,
LABS (INCLUDING BNP,
D-DIMER, CBC, METABOLIC
PROFILE) AND CXR
(BILATERAL PATCHY
INFILTRATES). TREATMENT
INCLUDED O2 PER NASAL
CANNULA TITRATED TO SATS,
SOLUMEDROL AND IV
BENADRYL X 1, AND
ANTIBIOTIC TREATMENT WITH
CEFTRIAZONE AND
AZITHROMYCIN WHICH WAS
COMPLETED WHILE IN
HOSPITAL. AT PHONE CALL,
SUBJECT REPORTED
IMPROVING SHORTNESS OF
AIR, COUGH, FATIGUE, AND
CONGESTION. WILL CONTINUE
TO FOLLOW.FINAL FOLLOW UP
WITH PCP 09DEC2020-LUNGS
CLEAR, NO FURTHER FOLLOW
UP OR CMS. AE CLOSED

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

US3312197

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 22 Apr 2021 20:40:06

Generated On: 09 Jun 2021 17:01:02

AEID	
Adverse event	PRE-DIABETES
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)	28 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

378 of 3104

US3312197

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 22 Apr 2021 20:40:06

Generated On: 09 Jun 2021 17:01:02

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

US3312197

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 22 Apr 2021 20:40:06

Generated On: 09 Jun 2021 17:01:02

AEID	
Adverse event	SPINAL DISC HERNIATION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	05 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

380 of 3104

US3312197

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 22 Apr 2021 20:40:06

Generated On: 09 Jun 2021 17:01:02

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

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 05 Apr 2021 21:14:12

Generated On: 09 Jun 2021 17:01:02

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

Yes ☒

No ☐

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 22 Apr 2021 20:40:07

Generated On: 09 Jun 2021 17:01:02

Name of Medication TAMULOSIN

Prophylaxis Yes ☐
No ☒

Indication BENIGN PROSTATIC
HYPERPLASIA

Dose per administration 0.4

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

383 of 3104

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 22 Apr 2021 20:40:07

Generated On: 09 Jun 2021 17:01:02

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

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 22 Apr 2021 20:40:07

Generated On: 09 Jun 2021 17:01:02

Name of Medication FLUOXETINE

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

385 of 3104

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 22 Apr 2021 20:40:07

Generated On: 09 Jun 2021 17:01:02

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2000	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 22 Apr 2021 20:40:07

Generated On: 09 Jun 2021 17:01:02

Name of Medication CORVEDIOL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

387 of 3104

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 22 Apr 2021 20:40:07

Generated On: 09 Jun 2021 17:01:02

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

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 22 Apr 2021 20:40:07

Generated On: 09 Jun 2021 17:01:02

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 80

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

389 of 3104

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 22 Apr 2021 20:40:07

Generated On: 09 Jun 2021 17:01:02

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

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 22 Apr 2021 20:40:07

Generated On: 09 Jun 2021 17:01:02

Name of Medication APIXABAN

Prophylaxis Yes ☐
No ☒

Indication ATRIL FIBRILLATION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

391 of 3104

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 22 Apr 2021 20:40:07

Generated On: 09 Jun 2021 17:01:02

	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"/>

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 22 Apr 2021 20:40:07

Generated On: 09 Jun 2021 17:01:02

Name of Medication PANTOPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication GASTROESOPHAGEAL REFLUX
DISEASE

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

393 of 3104

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 22 Apr 2021 20:40:07

Generated On: 09 Jun 2021 17:01:02

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

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 22 Apr 2021 20:40:07

Generated On: 09 Jun 2021 17:01:02

Name of Medication MONTELUKAST

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

395 of 3104

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 22 Apr 2021 20:40:07

Generated On: 09 Jun 2021 17:01:02

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

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 22 Apr 2021 20:40:07

Generated On: 09 Jun 2021 17:01:02

Name of Medication VITAMIN D

Prophylaxis Yes ☒
No ☐

Indication HEALTH PROPHYLAXIS

Dose per administration 1000

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

397 of 3104

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 22 Apr 2021 20:40:07

Generated On: 09 Jun 2021 17:01:02

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

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 22 Apr 2021 20:40:07

Generated On: 09 Jun 2021 17:01:02

Name of Medication ZYRTEC

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

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 ☐

PRODUCTION RELEASE (v12.003

399 of 3104

EAB) (1725)

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 22 Apr 2021 20:40:07

Generated On: 09 Jun 2021 17:01:02

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

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 22 Apr 2021 20:40:07

Generated On: 09 Jun 2021 17:01:02

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication CARDIAC PROPHYLAXIS

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

401 of 3104

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 22 Apr 2021 20:40:07

Generated On: 09 Jun 2021 17:01:02

	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"/>

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 22 Apr 2021 20:40:07

Generated On: 09 Jun 2021 17:01:02

Name of Medication SPIRONOLACTONE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

403 of 3104

EAB) (1725)

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 22 Apr 2021 20:40:07

Generated On: 09 Jun 2021 17:01:02

	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 type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	27 AUG 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 22 Apr 2021 20:40:07

Generated On: 09 Jun 2021 17:01:02

Name of Medication CHLORPHALIDONE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

405 of 3104

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 22 Apr 2021 20:40:07

Generated On: 09 Jun 2021 17:01:02

	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)	28 AUG 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"/>

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 22 Apr 2021 20:40:07

Generated On: 09 Jun 2021 17:01:02

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication EXACERBATION OF LEFT
RADICULOPATHY

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

407 of 3104

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 22 Apr 2021 20:40:07

Generated On: 09 Jun 2021 17:01:02

	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)	12 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)		12 SEP 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"/>

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 22 Apr 2021 20:40:07

Generated On: 09 Jun 2021 17:01:02

Name of Medication NAPROXEN

Prophylaxis Yes ☐
No ☒

Indication EXACERBATION OF LEFT
CERVICAL RADICULOPATHY

Dose per administration 220

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)

409 of 3104

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 22 Apr 2021 20:40:07

Generated On: 09 Jun 2021 17:01:02

	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)	12 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)		12 SEP 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"/>

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 22 Apr 2021 20:40:07

Generated On: 09 Jun 2021 17:01:02

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication EXACERBATION OF LEFT
CERVICAL RADICULOPATHY

Dose per administration 600

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)

411 of 3104

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 22 Apr 2021 20:40:07

Generated On: 09 Jun 2021 17:01:02

	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)	12 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)		13 SEP 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"/>

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 22 Apr 2021 20:40:07

Generated On: 09 Jun 2021 17:01:02

Name of Medication PERCOCET

Prophylaxis Yes ☐
No ☒

Indication EXACERBATION OF LEFT
CERVICAL RADICULOPATHY

Dose per administration 5/325

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

413 of 3104

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 22 Apr 2021 20:40:07

Generated On: 09 Jun 2021 17:01:02

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	14 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)	18 SEP 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"/>

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 22 Apr 2021 20:40:07

Generated On: 09 Jun 2021 17:01:02

Name of Medication ANDROGEL TESTOSTERONE
GEL 1.62%

Prophylaxis Yes ☐
No ☒

Indication LOW TESTOSTERONE LEVELS

Dose per administration 2

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

If dose unit is Other, specify PUMPS

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)

415 of 3104

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 22 Apr 2021 20:40:07

Generated On: 09 Jun 2021 17:01:02

	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)		04 JUN 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"/>

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 22 Apr 2021 20:40:07

Generated On: 09 Jun 2021 17:01:02

Name of Medication CYCLOBENZAPRINE

Prophylaxis Yes ☐
No ☒

Indication EXACERBATION OF LEFT
CERVICAL RADICULOPATHY

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

NIGHTLY

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003

417 of 3104

EAB) (1725)

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 22 Apr 2021 20:40:07

Generated On: 09 Jun 2021 17:01:02

	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 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)		09 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"/>

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 22 Apr 2021 20:40:07

Generated On: 09 Jun 2021 17:01:02

Name of Medication SEASONAL INFLUENZA
VACCINE

Prophylaxis Yes ☒
No ☐

Indication SEASONAL INFLUENZA
PROPHYLAXIS

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

419 of 3104

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 22 Apr 2021 20:40:07

Generated On: 09 Jun 2021 17:01:02

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input checked="" 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)	06 NOV 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 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 22 Apr 2021 20:40:07

Generated On: 09 Jun 2021 17:01:02

Name of Medication NAPROXEN

Prophylaxis Yes ☐
No ☒

Indication PNEUMONIA

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

421 of 3104

EAB) (1725)

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 22 Apr 2021 20:40:07

Generated On: 09 Jun 2021 17:01:02

	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)		22 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		27 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 22 Apr 2021 20:40:07

Generated On: 09 Jun 2021 17:01:02

Name of Medication LUDEN'S COUGH DROP (PECTIN 2.8MG)

Prophylaxis Yes ☐
No ☒

Indication PNEUMONIA

Dose per administration 1

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

If dose unit is Other, specify LOZENGE

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)

423 of 3104

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 22 Apr 2021 20:40:07

Generated On: 09 Jun 2021 17:01:02

	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)	22 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		30 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 22 Apr 2021 20:40:07

Generated On: 09 Jun 2021 17:01:02

Name of Medication PHENOL 1.4%

Prophylaxis Yes ☐
No ☒

Indication PENUMONIA

Dose per administration 2

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

If dose unit is Other, specify SPRAYS

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

425 of 3104

EAB) (1725)

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 22 Apr 2021 20:40:07

Generated On: 09 Jun 2021 17:01:02

	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	INTRA-ORAL-PHARYNGEAL	
Start date (dd MMM yyyy)	22 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	30 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 22 Apr 2021 20:40:07

Generated On: 09 Jun 2021 17:01:02

Name of Medication BILEVEL POSITIVE AIRWAY
PRESSURE

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

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 22 Apr 2021 20:40:07

Generated On: 09 Jun 2021 17:01:02

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" 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="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)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 22 Apr 2021 20:40:07

Generated On: 09 Jun 2021 17:01:02

Name of Medication AMOXICILLIN/CLAVULANATE

Prophylaxis Yes ☐
No ☒

Indication PNEUMONIA

Dose per administration 875/125

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

429 of 3104

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 22 Apr 2021 20:40:07

Generated On: 09 Jun 2021 17:01:02

	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)	25 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	30 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 22 Apr 2021 20:40:07

Generated On: 09 Jun 2021 17:01:02

Name of Medication METFORMIN HCL

Prophylaxis Yes ☐
No ☒

Indication PRE-DIABETES

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

431 of 3104

EAB) (1725)

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 22 Apr 2021 20:40:07

Generated On: 09 Jun 2021 17:01:02

	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)	29 DEC 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"/>

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 22 Apr 2021 20:40:07

Generated On: 09 Jun 2021 17:01:02

Name of Medication SOLUMEDROL

Prophylaxis Yes ☐
No ☒

Indication PNEUMONIA

Dose per administration UNK

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

433 of 3104

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 22 Apr 2021 20:40:07

Generated On: 09 Jun 2021 17:01:02

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	28 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)	28 NOV 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input type="checkbox"/>	

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 22 Apr 2021 20:40:07

Generated On: 09 Jun 2021 17:01:02

Name of Medication BENADRYL

Prophylaxis Yes ☐
No ☒

Indication PNEUMONIA

Dose per administration UNK

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

435 of 3104

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 22 Apr 2021 20:40:07

Generated On: 09 Jun 2021 17:01:02

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	28 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 22 Apr 2021 20:40:07

Generated On: 09 Jun 2021 17:01:02

Name of Medication CEFTRIAXONE

Prophylaxis Yes ☐
No ☒

Indication PNEUMONIA

Dose per administration UNK

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

437 of 3104

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 22 Apr 2021 20:40:07

Generated On: 09 Jun 2021 17:01:02

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	28 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	01 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 22 Apr 2021 20:40:07

Generated On: 09 Jun 2021 17:01:02

Name of Medication AZITHROMYCIN

Prophylaxis Yes ☐
No ☒

Indication PNEUMONIA

Dose per administration UNK

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

439 of 3104

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 22 Apr 2021 20:40:07

Generated On: 09 Jun 2021 17:01:02

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	28 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	01 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 22 Apr 2021 20:40:07

Generated On: 09 Jun 2021 17:01:02

Name of Medication OXYGEN

Prophylaxis Yes ☐
No ☒

Indication PNEUMONIA

Dose per administration 2

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

If dose unit is Other, specify LITERS

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

If frequency is Other, specify CONTINUOUS

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

PRODUCTION RELEASE (v12.003

441 of 3104

EAB) (1725)

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 22 Apr 2021 20:40:07

Generated On: 09 Jun 2021 17:01:02

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	NASAL CANNULA	
Start date (dd MMM yyyy)	28 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	30 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 22 Apr 2021 20:40:07

Generated On: 09 Jun 2021 17:01:02

Name of Medication TRAMADOL

Prophylaxis Yes ☐
No ☒

Indication SPINAL DISC HERNIATION

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)

443 of 3104

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 22 Apr 2021 20:40:07

Generated On: 09 Jun 2021 17:01:02

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		08 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		10 APR 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"/>

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 22 Apr 2021 20:40:07

Generated On: 09 Jun 2021 17:01:02

Name of Medication OXYCODONE

Prophylaxis Yes ☐
No ☒

Indication SPINAL DISC HERNIATION

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 ☐

PRODUCTION RELEASE (v12.003

445 of 3104

EAB) (1725)

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 22 Apr 2021 20:40:07

Generated On: 09 Jun 2021 17:01:02

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	10 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 22 Apr 2021 20:40:07

Generated On: 09 Jun 2021 17:01:02

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication SPINAL DISC HERNIATION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

447 of 3104

EAB) (1725)

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 22 Apr 2021 20:40:07

Generated On: 09 Jun 2021 17:01:02

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	10 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3312197

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 05 Apr 2021 21:14:12

Generated On: 09 Jun 2021 17:01:02

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3312197

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 05 Apr 2021 21:14:12

Generated On: 09 Jun 2021 17:01:02

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
28 NOV 2020	ELECTROCARDIOGRAM	Adverse Event	
28 NOV 2020	CHEST X-RAY	Adverse Event	

US3312197

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 05 Apr 2021 21:14:13

Generated On: 09 Jun 2021 17:01:02

Date of dosing discontinuation (dd MMM yyyy) 17 SEP 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#2

US3312197

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:01:02

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 ☐

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Data signed: (b) (4) 05 Apr 2021 21:14:40

Generated On: 09 Jun 2021 17:01:02

SAEID	USA-US300-2020-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	LENEXA
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form (1)

Data signed: (b) (4) 05 Apr 2021 21:14:40

Generated On: 09 Jun 2021 17:01:02

SAEID	USA-US300-2020-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	LENEXA
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	01/DEC/2020 08:42
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

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form (2)

Data signed: (b) (4) 05 Apr 2021 21:14:40

Generated On: 09 Jun 2021 17:01:02

SAEID	USA-US300-2020-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	LENEXA
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	09/DEC/2020 18:23
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

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form (3)

Data signed: (b) (4) 05 Apr 2021 21:14:40

Generated On: 09 Jun 2021 17:01:02

SAEID	USA-US300-2020-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	LENEXA
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	18/DEC/2020 14:38
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

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form (4)

Data signed: (b) (4) 05 Apr 2021 21:14:40

Generated On: 09 Jun 2021 17:01:02

SAEID	USA-US300-2020-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	LENEXA
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	22/DEC/2020 16:36
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

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form (5)

Data signed: (b) (4) 05 Apr 2021 21:14:40

Generated On: 09 Jun 2021 17:01:02

SAEID	USA-US300-2020-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	LENEXA
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	28/DEC/2020 14:02
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

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form (6)

Data signed: (b) (4) 05 Apr 2021 21:14:40

Generated On: 09 Jun 2021 17:01:02

SAEID	USA-US300-2020-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	LENEXA
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	12/JAN/2021 16:47
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form (7)

Data signed: (b) (4) 05 Apr 2021 21:14:40

Generated On: 09 Jun 2021 17:01:02

SAEID	USA-US300-2020-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	LENEXA
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	02/FEB/2021 10:58
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form (8)

Data signed: (b) (4) 05 Apr 2021 21:14:40

Generated On: 09 Jun 2021 17:01:02

SAEID	USA-US300-2020-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	LENEXA
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	17/FEB/2021 11:06
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3312197 (Prod: Johnson County Clin-Trials)

US3312197

Form: Participant Creation

Generated On: 09 Jun 2021 17:01:02

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'US3312197'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	20 Aug 2020 18:34:17

US3312197

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:01:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'Yes (Y)'	(b) (4) Christa Estrada (b) (4)	20 Aug 2020 19:56:02

US3312197

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '20 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	20 Aug 2020 18:34:18

US3312197

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:01:02

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'Clinic (Clinic)'	Christa Estrada (b) (4)	20 Aug 2020 19:56:02

US3312197

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:01:02

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered 'SCRN'	System	20 Aug 2020 19:56:02

US3312197

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:01:02

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered (b) (6) 1950'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	20 Aug 2020 18:34:19

US3312197

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:01:02

Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User closed query 'Per DMR: Since the Inclusion/exclusion Criteria Summary form has been updated, kindly consider to complete the demographics form .Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Aug 2020 19:23:17
Query 'Per DMR: Since the Inclusion/exclusion Criteria Summary form has been updated, kindly consider to complete the demographics form .Thank you.' answered with 'updated' (Site from DM).	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:27:50
User entered '69'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:27:42
User opened query 'Per DMR: Since the Inclusion/exclusion Criteria Summary form has been updated, kindly consider to complete the demographics form .Thank you.' (Site from DM).	(b) (4), (b) (6)	27 Aug 2020 05:50:22

US3312197

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:01:02

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered 'YEARS'	System	28 Aug 2020 18:27:42

US3312197

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:01:02

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered '69'	System	20 Aug 2020 19:56:18

US3312197

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:01:02

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'Male (M)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:27:42

US3312197

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:01:02

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:27:42

US3312197

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:01:02

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'I'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:27:42

US3312197

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:01:02

Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:27:42

US3312197

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:01:02

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:27:42

US3312197

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:01:02

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:27:42

US3312197

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:01:02

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:27:42

US3312197

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:01:02

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:27:42

US3312197

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:01:02

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:27:42

US3312197

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:01:02

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:27:42

US3312197

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:01:02

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:27:42

US3312197

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:01:02

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '20 Aug 2020'	Christa Estrada (b) (4)	20 Aug 2020 19:56:18

US3312197

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered 'Aug 2020'	System	20 Aug 2020 19:56:18

US3312197

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered '2020'	System	20 Aug 2020 19:56:18

US3312197

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:01:02

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'Amendment 2 (2)'	Christa Estrada (b) (4)	20 Aug 2020 19:56:18

US3312197

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:01:02

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'Yes (Y)'	Christa Estrada (b) (4)	20 Aug 2020 19:56:18

US3312197

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:01:02

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered empty.	Christa Estrada (b) (4)	20 Aug 2020 19:56:18

US3312197

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:01:02

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered empty.	(b) (4) Christa Estrada (b) (4)	20 Aug 2020 19:56:18

US3312197

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:01:02

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'No (N)'	(b) (4) Christa Estrada (b) (4)	20 Aug 2020 19:56:18

US3312197

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:01:02

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	20 Aug 2020 18:34:18

US3312197

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:01:02

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered 'I'	System	20 Aug 2020 19:56:26

US3312197

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:01:02

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'Yes (Y)'	(b) (4) Christa Estrada (b) (4)	20 Aug 2020 19:56:26

US3312197

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:01:02

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:28:04

US3312197

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:01:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic neoplasms and hypertrophy, PT: Benign prostatic hyperplasia, LLT: Benign prostatic hyperplasia - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 18:29:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 18:29:45
Data point term sent to Coder	System	28 Aug 2020 18:28:39
User entered 'Benign prostatic hyperplasia'	Karol Moore (b) (4)	28 Aug 2020 18:28:37

US3312197

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'un UNK 2018'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:28:37

US3312197

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:01:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:28:37

US3312197

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:01:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:28:37

US3312197

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:01:02

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:28:37

US3312197

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:01:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:28:37

US3312197

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:01:02

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered 'Jan 2018'	System	28 Aug 2020 18:28:37

US3312197

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:01:02

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered '2018'	System	28 Aug 2020 18:28:37

US3312197

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:01:02

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered empty.	System	28 Aug 2020 18:28:37

US3312197

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:01:02

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered empty.	System	28 Aug 2020 18:28:37

US3312197

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:01:02

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 18:30:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 18:30:47
Data point term sent to Coder	System	28 Aug 2020 18:29:39
User entered 'anxiety'	Karol Moore (b) (4)	28 Aug 2020 18:28:48
	(b) (4)	

US3312197

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'un UNK 2000'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:28:48

US3312197

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:01:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:28:48

US3312197

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:01:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:28:48

US3312197

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:01:02

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:28:48

US3312197

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:01:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:28:48

US3312197

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:01:02

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered 'Jan 2000'	System	28 Aug 2020 18:28:48

US3312197

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:01:02

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered '2000'	System	28 Aug 2020 18:28:48

US3312197

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:01:02

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered empty.	System	28 Aug 2020 18:28:48

US3312197

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:01:02

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered empty.	System	28 Aug 2020 18:28:48

US3312197

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:01:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 18:30:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 18:30:47
Data point term sent to Coder	System	28 Aug 2020 18:29:39
User entered 'hypertension'	Karol Moore (b) (4)	28 Aug 2020 18:29:01

US3312197

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'un UNK 2010'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:29:01

US3312197

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:01:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:29:01

US3312197

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:01:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:29:01

US3312197

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:01:02

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered empty.	(b) (4) Karol Moore (b) (4)	28 Aug 2020 18:29:01

US3312197

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:01:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:29:01

US3312197

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:01:02

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered 'Jan 2010'	System	28 Aug 2020 18:29:01

US3312197

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:01:02

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered '2010'	System	28 Aug 2020 18:29:01

US3312197

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:01:02

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered empty.	System	28 Aug 2020 18:29:01

US3312197

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:01:02

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered empty.	System	28 Aug 2020 18:29:01

US3312197

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:01:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 18:30:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 18:30:46
Data point term sent to Coder	System	28 Aug 2020 18:29:41
User entered 'hyperlipidemia'	Karol Moore (b) (4)	28 Aug 2020 18:29:15

US3312197

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'un UNK 2010'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:29:15

US3312197

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:01:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:29:15

US3312197

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:01:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:29:15

US3312197

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:01:02

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered empty.	(b) (4) Karol Moore (b) (4)	28 Aug 2020 18:29:15

US3312197

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:01:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:29:15

US3312197

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:01:02

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered 'Jan 2010'	System	28 Aug 2020 18:29:15

US3312197

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:01:02

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered '2010'	System	28 Aug 2020 18:29:15

US3312197

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:01:02

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered empty.	System	28 Aug 2020 18:29:15

US3312197

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:01:02

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered empty.	System	28 Aug 2020 18:29:15

US3312197

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:01:02

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation - version MedDRA\23.0.	Coder Import (b) (4)	28 Aug 2020 20:03:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	28 Aug 2020 20:03:49
Data point term sent to Coder	System	28 Aug 2020 18:29:41
User entered 'atril fibrillation'	Karol Moore (b) (4)	28 Aug 2020 18:29:30

US3312197

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'un UNK 2017'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:29:30

US3312197

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:01:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:29:30

US3312197

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:01:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:29:30

US3312197

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:01:02

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:29:30

US3312197

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:01:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:29:30

US3312197

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:01:02

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered 'Jan 2017'	System	28 Aug 2020 18:29:30

US3312197

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:01:02

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered '2017'	System	28 Aug 2020 18:29:30

US3312197

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:01:02

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered empty.	System	28 Aug 2020 18:29:30

US3312197

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:01:02

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered empty.	System	28 Aug 2020 18:29:30

US3312197

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:01:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
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)	28 Aug 2020 18:31:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 18:31:50
Data point term sent to Coder	System	28 Aug 2020 18:30:42
User entered 'Gastroesophageal reflux disease'	Karol Moore (b) (4)	28 Aug 2020 18:29:52

US3312197

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'un UNK 2018'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:29:52

US3312197

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:01:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:29:52

US3312197

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:01:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:29:52

US3312197

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:01:02

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:29:52

US3312197

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:01:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:29:52

US3312197

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:01:02

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered 'Jan 2018'	System	28 Aug 2020 18:29:52

US3312197

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:01:02

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered '2018'	System	28 Aug 2020 18:29:52

US3312197

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:01:02

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered empty.	System	28 Aug 2020 18:29:52

US3312197

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:01:02

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered empty.	System	28 Aug 2020 18:29:52

US3312197

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:01:02

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 18:31:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 18:31:49
Data point term sent to Coder	System	28 Aug 2020 18:30:42
User entered 'seasonal allergies'	Karol Moore (b) (4)	28 Aug 2020 18:30:09

US3312197

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'un UNK 1980'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:30:09

US3312197

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:01:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:30:09

US3312197

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:01:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:30:09

US3312197

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:01:02

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:30:09

US3312197

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:01:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:30:09

US3312197

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:01:02

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered 'Jan 1980'	System	28 Aug 2020 18:30:09

US3312197

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:01:02

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered '1980'	System	28 Aug 2020 18:30:09

US3312197

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:01:02

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered empty.	System	28 Aug 2020 18:30:09

US3312197

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:01:02

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered empty.	System	28 Aug 2020 18:30:09

US3312197

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:01:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User coded data point as SOC: Cardiac disorders, HLT: Ischaemic coronary artery disorders, PT: Myocardial infarction, LLT: Myocardial infarction - version MedDRA\\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 18:31:50
Data point term sent to Coder	(b) (4)	
User entered 'Myocardial Infarction'	Karol Moore (b) (4)	28 Aug 2020 18:30:43
	(b) (4)	28 Aug 2020 18:30:40

US3312197

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'un May 2017'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:30:40

US3312197

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:01:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:30:40

US3312197

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:01:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User closed query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	(b) (4) System	28 Aug 2020 18:30:48
User entered 'No (N)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:30:48
User opened query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	System	28 Aug 2020 18:30:40
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:30:40

US3312197

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:01:02

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'un May 2017'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:30:40

US3312197

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:01:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:30:40

US3312197

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:01:02

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered 'May 2017'	System	28 Aug 2020 18:30:40

US3312197

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:01:02

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered '2017'	System	28 Aug 2020 18:30:40

US3312197

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:01:02

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered 'May 2017'	System	28 Aug 2020 18:30:40

US3312197

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:01:02

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered '2017'	System	28 Aug 2020 18:30:40

US3312197

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:01:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User coded data point as SOC: Surgical and medical procedures, HLGT: Vascular therapeutic procedures, HLT: Arterial therapeutic procedures (excl aortic), PT: Coronary arterial stent insertion, LLT: Coronary stent placement - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 18:32:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 18:32:51
Data point term sent to Coder	System	28 Aug 2020 18:31:44
User entered 'cardiac stent placement'	Karol Moore (b) (4)	28 Aug 2020 18:31:08

US3312197

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'un May 2017'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:31:08

US3312197

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:01:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:31:08

US3312197

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:01:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:31:08

US3312197

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:01:02

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'un May 2017'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:31:08

US3312197

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:01:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:31:08

US3312197

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:01:02

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered 'May 2017'	System	28 Aug 2020 18:31:08

US3312197

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:01:02

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered '2017'	System	28 Aug 2020 18:31:08

US3312197

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:01:02

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered 'May 2017'	System	28 Aug 2020 18:31:08

US3312197

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:01:02

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered '2017'	System	28 Aug 2020 18:31:08

US3312197

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:01:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Mononeuropathies, PT: Carpal tunnel syndrome, LLT: Carpal tunnel syndrome - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 18:32:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 18:32:52
Data point term sent to Coder	System	28 Aug 2020 18:31:44
User entered 'bilateral carpal tunnel'	Karol Moore (b) (4)	28 Aug 2020 18:31:26

US3312197

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'un UNK 2007'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:31:26

US3312197

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:01:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:31:26

US3312197

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:01:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	28 Aug 2020 18:31:26

US3312197

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:01:02

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'un UNK 2007'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:31:26

US3312197

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:01:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:31:26

US3312197

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:01:02

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered 'Jan 2007'	System	28 Aug 2020 18:31:26

US3312197

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:01:02

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered '2007'	System	28 Aug 2020 18:31:26

US3312197

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:01:02

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered 'Jan 2007'	System	28 Aug 2020 18:31:26

US3312197

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:01:02

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered '2007'	System	28 Aug 2020 18:31:26

US3312197

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:01:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Peripheral nerve therapeutic procedures, PT: Carpal tunnel decompression, LLT: Carpal tunnel release - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 18:33:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 18:33:38
Data point term sent to Coder	System	28 Aug 2020 18:32:47
User entered 'bilateral carpal tunnel repair'	Karol Moore (b) (4)	28 Aug 2020 18:31:49

US3312197

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'un UNK 2007'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:31:49

US3312197

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:01:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:31:49

US3312197

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:01:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:31:49

US3312197

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:01:02

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'un UNK 2007'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:31:49

US3312197

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:01:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:31:49

US3312197

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:01:02

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered 'Jan 2007'	System	28 Aug 2020 18:31:49

US3312197

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:01:02

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered '2007'	System	28 Aug 2020 18:31:49

US3312197

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:01:02

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered 'Jan 2007'	System	28 Aug 2020 18:31:49

US3312197

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:01:02

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered '2007'	System	28 Aug 2020 18:31:49

US3312197

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:01:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Spine and neck deformities, PT: Spinal stenosis, LLT: Spinal stenosis - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 18:33:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 18:33:39
Data point term sent to Coder	System	28 Aug 2020 18:32:47
User entered 'spinal stenosis'	Karol Moore (b) (4)	28 Aug 2020 18:32:06

US3312197

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'un UNK 1990'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:32:06

US3312197

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:01:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:32:06

US3312197

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:01:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:32:06

US3312197

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:01:02

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'un UNK 2012'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:32:06

US3312197

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:01:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:32:06

US3312197

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:01:02

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered 'Jan 1990'	System	28 Aug 2020 18:32:06

US3312197

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:01:02

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered '1990'	System	28 Aug 2020 18:32:06

US3312197

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:01:02

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered 'Jan 2012'	System	28 Aug 2020 18:32:06

US3312197

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:01:02

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered '2012'	System	28 Aug 2020 18:32:06

US3312197

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:01:02

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Spine and spinal cord therapeutic procedures, PT: Spinal laminectomy, LLT: Spinal laminectomy - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 18:33:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 18:33:38
Data point term sent to Coder	System	28 Aug 2020 18:32:49
User entered 'spinal laminectomy'	Karol Moore (b) (4)	28 Aug 2020 18:32:23

US3312197

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'un UNK 2012'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:32:23

US3312197

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:01:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:32:23

US3312197

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:01:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:32:23

US3312197

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:01:02

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'un UNK 2012'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:32:23

US3312197

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:01:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:32:23

US3312197

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:01:02

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered 'Jan 2012'	System	28 Aug 2020 18:32:23

US3312197

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:01:02

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered '2012'	System	28 Aug 2020 18:32:23

US3312197

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:01:02

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered 'Jan 2012'	System	28 Aug 2020 18:32:23

US3312197

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:01:02

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered '2012'	System	28 Aug 2020 18:32:23

US3312197

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:01:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related disorders NEC, PT: Rotator cuff syndrome, LLT: Rotator cuff tear - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 18:33:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 18:33:39
Data point term sent to Coder	System	28 Aug 2020 18:32:49
User entered 'right rotator cuff tear'	Karol Moore (b) (4)	28 Aug 2020 18:32:47

US3312197

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'un Mar 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:32:47

US3312197

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:01:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:32:47

US3312197

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:01:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	28 Aug 2020 18:33:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Aug 2020 18:33:17
User entered 'No (N)' reason for change: Data Entry Error	Karol Moore (b) (4)	28 Aug 2020 18:33:17
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	28 Aug 2020 18:32:47
User entered empty.	System	28 Aug 2020 18:32:47
	Karol Moore (b) (4)	28 Aug 2020 18:32:47
	(b) (4)	

US3312197

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:01:02

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'un Mar 2020'	(b) (4) Karol Moore (b) (4)	28 Aug 2020 18:32:47

US3312197

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:01:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:32:47

US3312197

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:01:02

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered 'Mar 2020'	System	28 Aug 2020 18:32:47

US3312197

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:01:02

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered '2020'	System	28 Aug 2020 18:32:47

US3312197

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:01:02

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered 'Mar 2020'	System	28 Aug 2020 18:32:47

US3312197

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:01:02

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered '2020'	System	28 Aug 2020 18:32:47

US3312197

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:01:02

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Rotator cuff repair, LLT: Rotator cuff repair - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 18:34:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 18:34:40
Data point term sent to Coder	System	28 Aug 2020 18:33:49
User entered 'right rotator cuff repair'	Karol Moore (b) (4)	28 Aug 2020 18:33:12

US3312197

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'un May 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:33:12

US3312197

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:01:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:33:12

US3312197

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:01:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:33:12

US3312197

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:01:02

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'un May 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:33:12

US3312197

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:01:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:33:12

US3312197

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:01:02

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered 'May 2020'	System	28 Aug 2020 18:33:12

US3312197

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:01:02

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered '2020'	System	28 Aug 2020 18:33:12

US3312197

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:01:02

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered 'May 2020'	System	28 Aug 2020 18:33:12

US3312197

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:01:02

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered '2020'	System	28 Aug 2020 18:33:12

US3312197

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:01:02

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Breast disorders, HLT: Breast disorders NEC, PT: Gynaecomastia, LLT: Gynaecomastia - version MedDRA\\23.0.	Coder Import (b) (4)	21 Sep 2020 22:03:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Sep 2020 22:03:48
Data point term sent to Coder	System	21 Sep 2020 22:02:28
User entered 'GYNECOMASTIA'	Karol Moore (b) (4)	21 Sep 2020 22:01:46
	(b) (4)	

US3312197

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'UN UNK 2018'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:01:46

US3312197

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:01:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:01:46

US3312197

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:01:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:01:46

US3312197

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:01:02

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:01:46

US3312197

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:01:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:01:46

US3312197

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:01:02

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered 'Jan 2018'	System	21 Sep 2020 22:01:46

US3312197

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:01:02

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered '2018'	System	21 Sep 2020 22:01:46

US3312197

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:01:02

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered empty.	System	21 Sep 2020 22:01:46

US3312197

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:01:02

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered empty.	System	21 Sep 2020 22:01:46

US3312197

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:01:02

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	22 Sep 2020 05:49:55
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	22 Sep 2020 05:49:55
Data point term sent to Coder	System	21 Sep 2020 22:02:28
User entered 'OSTEOARTHRITIS OF NECK AND SHOULDERS'	Karol Moore (b) (4)	21 Sep 2020 22:02:10

US3312197

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'UN UNK 2000'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:02:10

US3312197

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:01:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:02:10

US3312197

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:01:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:02:10

US3312197

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:01:02

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered empty.	(b) (4) Karol Moore (b) (4)	21 Sep 2020 22:02:10

US3312197

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:01:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:02:10

US3312197

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:01:02

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered 'Jan 2000'	System	21 Sep 2020 22:02:10

US3312197

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:01:02

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered '2000'	System	21 Sep 2020 22:02:10

US3312197

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:01:02

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered empty.	System	21 Sep 2020 22:02:10

US3312197

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:01:02

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered empty.	System	21 Sep 2020 22:02:10

US3312197

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:01:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User coded data point as SOC: Investigations, HLGt: Endocrine investigations (incl sex hormones), HLT: Reproductive hormone analyses, PT: Blood testosterone decreased, LLT: Testosterone low - version MedDRA\\23.0.	Coder Import (b) (4)	21 Sep 2020 22:03:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Sep 2020 22:03:49
Data point term sent to Coder	System	21 Sep 2020 22:02:29
User entered 'LOW TESTOSTERONE LEVELS'	Karol Moore (b) (4)	21 Sep 2020 22:02:27

US3312197

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'UN Jan 2019'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:02:27

US3312197

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:01:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:02:27

US3312197

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:01:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:02:27

US3312197

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:01:02

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:02:27

US3312197

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:01:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:02:27

US3312197

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:01:02

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered 'Jan 2019'	System	21 Sep 2020 22:02:27

US3312197

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:01:02

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered '2019'	System	21 Sep 2020 22:02:27

US3312197

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:01:02

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered empty.	System	21 Sep 2020 22:02:27

US3312197

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:01:02

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered empty.	System	21 Sep 2020 22:02:27

US3312197

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:01:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User coded data point as SOC: Nervous system disorders, HLGT: Spinal cord and nerve root disorders, HLT: Cervical spinal cord and nerve root disorders, PT: Cervical radiculopathy, LLT: Cervical radiculopathy - version MedDRA\\23.0.	Coder Import (b) (4)	22 Sep 2020 00:21:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	22 Sep 2020 00:21:50
Data point term sent to Coder	System	21 Sep 2020 22:04:30
User entered 'LEFT CERVICAL RADICULOPATHY'	Karol Moore (b) (4)	21 Sep 2020 22:03:31

US3312197

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'UN UNK 2018'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:03:31

US3312197

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:01:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:03:31

US3312197

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:01:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:03:31

US3312197

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:01:02

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered empty.	(b) (4) Karol Moore (b) (4)	21 Sep 2020 22:03:31

US3312197

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:01:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:03:31

US3312197

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:01:02

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered 'Jan 2018'	System	21 Sep 2020 22:03:31

US3312197

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:01:02

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered '2018'	System	21 Sep 2020 22:03:31

US3312197

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:01:02

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered empty.	System	21 Sep 2020 22:03:31

US3312197

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:01:02

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered empty.	System	21 Sep 2020 22:03:31

US3312197

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:01:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
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 compression, LLT: Intervertebral disc compression - version MedDRA\\23.0.	Coder Import (b) (4)	22 Sep 2020 05:07:55
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	22 Sep 2020 05:07:55
Data point term sent to Coder	System	21 Sep 2020 22:04:30
User entered 'COMPRESSED CERVICAL DISC'	Karol Moore (b) (4)	21 Sep 2020 22:03:47

US3312197

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'UN UNK 2014'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:03:47

US3312197

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:01:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:03:47

US3312197

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:01:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:03:47

US3312197

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:01:02

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:03:47

US3312197

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:01:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:03:47

US3312197

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:01:02

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered 'Jan 2014'	System	21 Sep 2020 22:03:47

US3312197

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:01:02

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered '2014'	System	21 Sep 2020 22:03:47

US3312197

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:01:02

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered empty.	System	21 Sep 2020 22:03:47

US3312197

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:01:02

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered empty.	System	21 Sep 2020 22:03:47

US3312197

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:01:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User coded data point as SOC: Nervous system disorders, HLGT: Cranial nerve disorders (excl neoplasms), HLT: Olfactory nerve disorders, PT: Anosmia, LLT: Anosmia - version MedDRA\\23.0.	Coder Import (b) (4)	25 Nov 2020 23:45:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Nov 2020 23:45:59
Data point term sent to Coder	System	25 Nov 2020 23:45:18
User closed query 'For coding purposes, please split to report each event separately, in different entries (one event per line) to capture coding for all terms. ' (Site from System).	System	25 Nov 2020 23:44:39
Query 'For coding purposes, please split to report each event separately, in different entries (one event per line) to capture coding for all terms. ' answered with 'UPDATED' (Site from System).	Karol Moore (b) (4)	25 Nov 2020 23:44:39
User entered 'ANOSMIA' reason for change: Data Entry Error	Karol Moore (b) (4)	25 Nov 2020 23:44:33
User opened query 'For coding purposes, please split to report each event separately, in different entries (one event per line) to capture coding for all terms. ' (Site from System).	Coder Import (b) (4)	25 Nov 2020 22:04:56
Data point term sent to Coder	System	25 Nov 2020 21:38:28
User entered 'ANOSMIA (SECONDARY TO AGENT ORAGNE EXPOSURE)'	Karol Moore (b) (4)	25 Nov 2020 21:38:21

US3312197

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'UN UNK 1969'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:38:21

US3312197

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:01:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:38:21

US3312197

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:01:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:38:21

US3312197

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:01:02

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered empty.	(b) (4) Karol Moore (b) (4)	25 Nov 2020 21:38:21

US3312197

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:01:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:38:21

US3312197

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:01:02

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered 'Jan 1969'	System	25 Nov 2020 21:38:21

US3312197

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:01:02

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered '1969'	System	25 Nov 2020 21:38:21

US3312197

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:01:02

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered empty.	System	25 Nov 2020 21:38:21

US3312197

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:01:02

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered empty.	System	25 Nov 2020 21:38:21

US3312197

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:01:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Sleep apnea - version MedDRA\\23.0.	Coder Import (b) (4)	25 Nov 2020 21:41:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Nov 2020 21:41:04
Data point term sent to Coder	System	25 Nov 2020 21:39:29
User entered 'SLEEP APNEA'	Karol Moore (b) (4)	25 Nov 2020 21:38:32

US3312197

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'UN UNK 1990'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:38:32

US3312197

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:01:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:38:32

US3312197

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:01:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:38:32

US3312197

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:01:02

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:38:32

US3312197

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:01:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:38:32

US3312197

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:01:02

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered 'Jan 1990'	System	25 Nov 2020 21:38:32

US3312197

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:01:02

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered '1990'	System	25 Nov 2020 21:38:32

US3312197

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:01:02

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered empty.	System	25 Nov 2020 21:38:32

US3312197

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:01:02

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered empty.	System	25 Nov 2020 21:38:32

US3312197

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:01:02

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User coded data point as SOC: Psychiatric disorders, HLGTT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	08 Dec 2020 22:57:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Dec 2020 22:57:04
Data point term sent to Coder	System	08 Dec 2020 22:55:57
User entered 'depression'	(b) (4), (b) (6)	08 Dec 2020 22:55:46

US3312197

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'un UNK 2000'	(b) (4) (b) (4), (b) (6)	08 Dec 2020 22:55:46

US3312197

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:01:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Dec 2020 22:55:46

US3312197

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:01:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Dec 2020 22:55:46

US3312197

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:01:02

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 22:55:46

US3312197

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:01:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Dec 2020 22:55:46

US3312197

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:01:02

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered 'Jan 2000'	System	08 Dec 2020 22:55:46

US3312197

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:01:02

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered '2000'	System	08 Dec 2020 22:55:46

US3312197

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:01:02

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered empty.	System	08 Dec 2020 22:55:46

US3312197

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:01:02

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered empty.	System	08 Dec 2020 22:55:46

US3312197

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 17:01:02

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User coded data point as SOC: Cardiac disorders, HLG: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\\23.0.	Coder Import (b) (4)	08 Dec 2020 22:57:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Dec 2020 22:57:47
Data point term sent to Coder	System	08 Dec 2020 22:57:03
User entered 'coronary artery disease'	(b) (4), (b) (6)	08 Dec 2020 22:56:07

US3312197

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'un UNK 2017'	(b) (4) (b) (4), (b) (6)	08 Dec 2020 22:56:07

US3312197

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 17:01:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Dec 2020 22:56:07

US3312197

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 17:01:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Dec 2020 22:56:07

US3312197

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 17:01:02

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 22:56:07

US3312197

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 17:01:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Dec 2020 22:56:07

US3312197

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 17:01:02

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered 'Jan 2017'	System	08 Dec 2020 22:56:07

US3312197

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 17:01:02

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered '2017'	System	08 Dec 2020 22:56:07

US3312197

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 17:01:02

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered empty.	System	08 Dec 2020 22:56:07

US3312197

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 17:01:02

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered empty.	System	08 Dec 2020 22:56:07

US3312197

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:33:56

US3312197

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '20 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:33:56

US3312197

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '13:57'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:33:56

US3312197

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered '20 Aug 2020 13:57'	System	28 Aug 2020 18:33:56

US3312197

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '66' in	(b) (4) Karol Moore (b) (4)	28 Aug 2020 18:33:56
DataPoint set to visible.	(b) (4) System	20 Aug 2020 19:56:26

US3312197

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '249' lb	(b) (4) Karol Moore (b) (4)	28 Aug 2020 18:33:56
DataPoint set to visible.	(b) (4) System	20 Aug 2020 19:56:26

US3312197

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User closed query 'Per CDM: per sponsor review, BMI \geq 40 kg/m2 yet Severe obesity = No in Randomization Form. Please reconcile.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 06:24:29
Query 'Per CDM: per sponsor review, BMI \geq 40 kg/m2 yet Severe obesity = No in Randomization Form. Please reconcile.' answered with 'NA. CRITERIA ONLY TO BE SELECTED FOR PARTICIPANTS BETWEEN AGES ON 18-65. SUBJECT IS AUTOMATICALLY AT RISK ABOVE AGE OF 65' (Site from DM).	Karol Moore (b) (4) (b) (4)	07 Apr 2021 16:34:48
User opened query 'Per CDM: per sponsor review, BMI \geq 40 kg/m2 yet Severe obesity = No in Randomization Form. Please reconcile.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 05:32:48
User entered '40.27368'	System	28 Aug 2020 18:33:56
DataPoint set to visible.	System	20 Aug 2020 19:56:26

US3312197

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered 'kg/m2'	System	28 Aug 2020 18:33:56
DataPoint set to visible.	System	20 Aug 2020 19:56:26

US3312197

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	28 Aug 2020 18:33:56

US3312197

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:33:56

US3312197

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:33:56

US3312197

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	28 Aug 2020 18:33:56

US3312197

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered 'bpm'	System	28 Aug 2020 18:33:56

US3312197

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	28 Aug 2020 18:33:56

US3312197

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered 'breaths/min'	System	28 Aug 2020 18:33:56

US3312197

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	28 Aug 2020 18:33:56

US3312197

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered 'mmHg'	System	28 Aug 2020 18:33:56

US3312197

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	28 Aug 2020 18:33:56

US3312197

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User entered 'mmHg'	System	28 Aug 2020 18:33:56

US3312197

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17

US3312197

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17

US3312197

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:01:02

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:34:12

US3312197

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:01:02

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '20 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:34:12

US3312197

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:01:02

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:35:13

US3312197

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:01:02

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:35:13

US3312197

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:01:02

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)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:35:13

US3312197

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:01:02

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)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:35:13

US3312197

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:01:02

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	28 Aug 2020 18:35:13

US3312197

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:01:02

[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)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	28 Aug 2020 18:35:13

US3312197

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:01:02

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)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:35:13

US3312197

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:01:02

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)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:35:13

US3312197

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:01:02

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)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:35:13

US3312197

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:01:02

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)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:35:13

US3312197

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:01:02

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)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:35:13

US3312197

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:01:02

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:35:13

US3312197

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:01:02

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered empty.	(b) (4)	28 Aug 2020 18:35:13
	Karol Moore (b) (4)	
	(b) (4)	

US3312197

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:01:02

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:35:13

US3312197

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:01:02

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:35:13

US3312197

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:01:02

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)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:35:13

US3312197

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:01:02

[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)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:35:13

US3312197

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:01:02

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)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:35:13

US3312197

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:01:02

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '0'	(b) (4) Karol Moore (b) (4)	28 Aug 2020 18:35:13

US3312197

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:01:02

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'I'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:35:13

US3312197

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:01:02

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:55:17
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'resides in community with ongoing person to person trasnmission'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:35:13

US3312197

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:01:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'Yes (Y)'	(b) (4) Christa Estrada (b) (4)	20 Aug 2020 19:56:38

US3312197

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '20 Aug 2020'	(b) (4) Christa Estrada (b) (4)	20 Aug 2020 19:56:38

US3312197

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:01:02

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'Clinic (Clinic)'	(b) (4) Christa Estrada (b) (4) (b) (4)	20 Aug 2020 19:56:38

US3312197

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:01:02

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User entered 'VISIT1'	System	20 Aug 2020 19:56:38

US3312197

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '20 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	20 Aug 2020 19:24:27

US3312197

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:01:02

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 05:58:27
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:58:27
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	20 Aug 2020 19:24:27
User entered '187332' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	20 Aug 2020 19:24:27

US3312197

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:01:02

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	20 Aug 2020 19:24:27

US3312197

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:01:02

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)	03 Apr 2021 11:30:51
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'No (N)'	Christa Estrada (b) (4)	20 Aug 2020 19:56:58

US3312197

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:01:02

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)	03 Apr 2021 11:30:51
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'No (N)'	Christa Estrada (b) (4)	20 Aug 2020 19:56:58

US3312197

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:01:02

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'No (N)'	(b) (4) Christa Estrada (b) (4)	20 Aug 2020 19:56:58

US3312197

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:01:02

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'No (N)'	(b) (4) Christa Estrada (b) (4)	20 Aug 2020 19:56:58

US3312197

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:01:02

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'No (N)'	(b) (4) Christa Estrada (b) (4)	20 Aug 2020 19:56:58

US3312197

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:01:02

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	06 Oct 2020 18:30:50
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 10:37:18
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:49:04

US3312197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:01:02

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:36:29

US3312197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:01:02

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:36:29

US3312197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:01:02

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	28 Aug 2020 18:36:29

US3312197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:01:02

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:36:29

US3312197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:02

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User accepted default value 'Pre-Dose (PREDOSE)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:36:29

US3312197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:36:29

US3312197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '20 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:36:29

US3312197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '13:57'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:36:29

US3312197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:02

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User entered '20 Aug 2020 13:57'	System	28 Aug 2020 18:36:29

US3312197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '98.5' F	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:36:29

US3312197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:36:29

US3312197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:36:29

US3312197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '73'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:36:29

US3312197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User entered 'bpm'	System	28 Aug 2020 18:36:29

US3312197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:02

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '16'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:36:29

US3312197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User entered 'breaths/min'	System	28 Aug 2020 18:36:29

US3312197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '140'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:36:29

US3312197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User entered 'mmHg'	System	28 Aug 2020 18:36:29

US3312197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '79'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:36:29

US3312197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:02

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User entered 'mmHg'	System	28 Aug 2020 18:36:29

US3312197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:01:02

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:36:29

US3312197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:01:02

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:36:29

US3312197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:02

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User accepted default value 'Post-Dose (POSTDOSE)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:36:29

US3312197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:36:29

US3312197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '20 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:36:29

US3312197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '15:20'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:36:29

US3312197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:02

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User entered '20 Aug 2020 15:20'	System	28 Aug 2020 18:36:29

US3312197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '97.7' F	(b) (4)	28 Aug 2020 18:36:29
	Karol Moore (b) (4)	
	(b) (4)	

US3312197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:36:29

US3312197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:36:29

US3312197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '73'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:36:29

US3312197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User entered 'bpm'	System	28 Aug 2020 18:36:29

US3312197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:02

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '16'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:36:29

US3312197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User entered 'breaths/min'	System	28 Aug 2020 18:36:29

US3312197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '148'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:36:29

US3312197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User entered 'mmHg'	System	28 Aug 2020 18:36:29

US3312197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '73'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:36:29

US3312197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:02

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User entered 'mmHg'	System	28 Aug 2020 18:36:29

US3312197

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:01:02

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:36:41

US3312197

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:01:02

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:36:41

US3312197

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:01:02

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'Yes (Y)'	(b) (4) Christa Estrada (b) (4)	20 Aug 2020 19:57:22

US3312197

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:01:02

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered empty.	(b) (4) Christa Estrada (b) (4)	20 Aug 2020 19:57:22

US3312197

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:01:02

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)	03 Apr 2021 11:30:51
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered empty.	Christa Estrada (b) (4)	20 Aug 2020 19:57:22

US3312197

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:01:02

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User entered 'MRNA-1273 OR PLACEBO'	System	20 Aug 2020 19:57:22

US3312197

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:01:02

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '20 Aug 2020'	(b) (4) Christa Estrada (b) (4)	20 Aug 2020 19:57:22

US3312197

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:01:02

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '14:49'	(b) (4) Christa Estrada (b) (4)	20 Aug 2020 19:57:22

US3312197

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:01:02

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User entered '20 Aug 2020 14:49'	System	20 Aug 2020 19:57:22

US3312197

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:01:02

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'Left Arm (LEFT ARM)'	Christa Estrada (b) (4)	20 Aug 2020 19:57:22

US3312197

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:01:02

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User entered 'ONCE'	System	20 Aug 2020 19:57:22

US3312197

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:01:02

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User entered 'INTRAMUSCULAR'	System	20 Aug 2020 19:57:22

US3312197

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:01:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:37:01

US3312197

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:01:02

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '20 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:37:01

US3312197

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:01:02

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '14:14'	(b) (4)	28 Aug 2020 18:37:01
	Karol Moore (b) (4)	
	(b) (4)	

US3312197

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:01:02

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User entered '20 Aug 2020 14:14'	System	28 Aug 2020 18:37:01

US3312197

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:01:02

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '20 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:37:13

US3312197

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:01:02

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:37:13

US3312197

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:01:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:37:13

US3312197

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:01:02

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '14:12'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:37:13

US3312197

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:01:02

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User entered '20 Aug 2020 14:12'	System	28 Aug 2020 18:37:13

US3312197

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:01:02

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:37:13

US3312197

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:01:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:37:13

US3312197

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:01:02

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:37:13

US3312197

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:01:02

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User entered empty.	System	28 Aug 2020 18:37:13

US3312197

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:01:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:37:18

US3312197

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:01:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User entered 'I'	System	28 Aug 2020 18:37:18

US3312197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
Data entry locked.	System	20 Aug 2020 19:57:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 19:57:22

US3312197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:01:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-20T15:16:43', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '40021e21-833c-4016-812c-c54d9bd52599'	System	20 Aug 2020 20:17:15
User entered 'Yes (Y)'	System	20 Aug 2020 20:17:15

US3312197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:01:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-20T15:16:56', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '40021e21-833c-4016-812c-c54d9bd52599'	System	20 Aug 2020 20:17:15
User entered '97.7'	System	20 Aug 2020 20:17:15

US3312197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-20T15:17:03', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '40021e21-833c-4016-812c-c54d9bd52599'	System	20 Aug 2020 20:17:15
User entered 'No (N)'	System	20 Aug 2020 20:17:15

US3312197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:01:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-20T15:17:12', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '40021e21-833c-4016-812c-c54d9bd52599'	System	20 Aug 2020 20:17:15
User entered '20 Aug 2020 15:17'	System	20 Aug 2020 20:17:15

US3312197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
User entered '20 Aug 2020 15:09'	System	20 Aug 2020 19:57:22

US3312197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
User entered '20 Aug 2020 17:39'	System	20 Aug 2020 19:57:22

US3312197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
Data entry locked.	System	20 Aug 2020 19:57:22
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 19:57:22

US3312197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:01:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-20T18:34:39', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '30d0d022-b30d-4910-bfbc-4a427673f742'	System	20 Aug 2020 23:35:04
User entered 'Yes (Y)'	System	20 Aug 2020 23:35:04

US3312197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:01:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-20T18:34:50', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '30d0d022-b30d-4910-bfbc-4a427673f742' User entered '97.8'	System	20 Aug 2020 23:35:04
	System	20 Aug 2020 23:35:04

US3312197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-20T18:34:56', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '30d0d022-b30d-4910-bfbc-4a427673f742'	System	20 Aug 2020 23:35:04
User entered 'No (N)'	System	20 Aug 2020 23:35:04

US3312197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:01:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-20T18:35:02', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '30d0d022-b30d-4910-bfbc-4a427673f742'	System	20 Aug 2020 23:35:04
User entered '20 Aug 2020 18:35'	System	20 Aug 2020 23:35:04

US3312197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
User entered '20 Aug 2020 18:34'	System	20 Aug 2020 19:57:22

US3312197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 19:57:22

US3312197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
Data entry locked.	System	20 Aug 2020 19:57:22
User entered 'Day 2'	System	20 Aug 2020 19:57:22

US3312197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:01:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-21T14:51:03', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '3e951378-9899-46c2-a813-294665155c92'	System	21 Aug 2020 19:51:35
User entered 'Yes (Y)'	System	21 Aug 2020 19:51:35

US3312197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:01:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-21T14:51:10', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '3e951378-9899-46c2-a813-294665155c92'	System	21 Aug 2020 19:51:35
User entered '98.1'	System	21 Aug 2020 19:51:35

US3312197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-21T14:51:15', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '3e951378-9899-46c2-a813-294665155c92'	System	21 Aug 2020 19:51:35
User entered 'No (N)'	System	21 Aug 2020 19:51:35

US3312197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:01:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-21T14:51:28', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '3e951378-9899-46c2-a813-294665155c92'	System	21 Aug 2020 19:51:35
User entered '21 Aug 2020 14:51'	System	21 Aug 2020 19:51:35

US3312197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 19:57:22

US3312197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 19:57:22

US3312197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
Data entry locked.	System	20 Aug 2020 19:57:22
User entered 'Day 3'	System	20 Aug 2020 19:57:22

US3312197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:01:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-22T18:50:09', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'c77b5201-1b31-4799-99ca-00d1ccb654ee'	System	22 Aug 2020 23:50:28
User entered 'Yes (Y)'	System	22 Aug 2020 23:50:28

US3312197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:01:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-22T18:50:16', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'c77b5201-1b31-4799-99ca-00d1ccb654ee' User entered '98.3'	System	22 Aug 2020 23:50:28
	System	22 Aug 2020 23:50:28

US3312197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-22T18:50:21', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'c77b5201-1b31-4799-99ca-00d1ccb654ee'	System	22 Aug 2020 23:50:28
User entered 'No (N)'	System	22 Aug 2020 23:50:28

US3312197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:01:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-22T18:50:26', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'c77b5201-1b31-4799-99ca-00d1ccb654ee'	System	22 Aug 2020 23:50:28
User entered '22 Aug 2020 18:50'	System	22 Aug 2020 23:50:28

US3312197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 19:57:22

US3312197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 19:57:22

US3312197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
Data entry locked.	System	20 Aug 2020 19:57:22
User entered 'Day 4'	System	20 Aug 2020 19:57:22

US3312197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:01:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-23T18:35:38', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'c34ac812-b970-4f48-b1b0-e88f8e9a5ad1' User entered 'Yes (Y)'	System	23 Aug 2020 23:35:59
	System	23 Aug 2020 23:35:59

US3312197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:01:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-23T18:35:43', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'c34ac812-b970-4f48-b1b0-e88f8e9a5ad1' User entered '98.5'	System	23 Aug 2020 23:35:59
	System	23 Aug 2020 23:35:59

US3312197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-23T18:35:48', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'c34ac812-b970-4f48-b1b0-e88f8e9a5ad1'	System	23 Aug 2020 23:35:59
User entered 'No (N)'	System	23 Aug 2020 23:35:59

US3312197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:01:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-23T18:35:52', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'c34ac812-b970-4f48-b1b0-e88f8e9a5ad1'	System	23 Aug 2020 23:35:59
User entered '23 Aug 2020 18:35'	System	23 Aug 2020 23:35:59

US3312197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 19:57:22

US3312197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 19:57:22

US3312197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
Data entry locked.	System	20 Aug 2020 19:57:22
User entered 'Day 5'	System	20 Aug 2020 19:57:22

US3312197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:01:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-24T21:01:02', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'f7bb96d5-f674-4e0a-9c7f-5a36fdbf1219' User entered 'Yes (Y)'	System	25 Aug 2020 02:01:20
	System	25 Aug 2020 02:01:20

US3312197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:01:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-24T21:01:09', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'f7bb96d5-f674-4e0a-9c7f-5a36fdbf1219' User entered '98.5'	System	25 Aug 2020 02:01:20
	System	25 Aug 2020 02:01:20

US3312197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-24T21:01:13', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'f7bb96d5-f674-4e0a-9c7f-5a36fdbf1219'	System	25 Aug 2020 02:01:20
User entered 'No (N)'	System	25 Aug 2020 02:01:20

US3312197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:01:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-24T21:01:17', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'f7bb96d5-f674-4e0a-9c7f-5a36fdbf1219' User entered '24 Aug 2020 21:01'	System	25 Aug 2020 02:01:20
	System	25 Aug 2020 02:01:20

US3312197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 19:57:22

US3312197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 19:57:22

US3312197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
Data entry locked.	System	20 Aug 2020 19:57:22
User entered 'Day 6'	System	20 Aug 2020 19:57:22

US3312197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:01:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-25T18:36:45', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '4ef657ec-1a67-4437-a272-f25b23a3e96c'	System	25 Aug 2020 23:37:07
User entered 'Yes (Y)'	System	25 Aug 2020 23:37:07

US3312197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:01:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-25T18:36:53', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '4ef657ec-1a67-4437-a272-f25b23a3e96c' User entered '98.1'	System	25 Aug 2020 23:37:07
	System	25 Aug 2020 23:37:07

US3312197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-25T18:36:58', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '4ef657ec-1a67-4437-a272-f25b23a3e96c'	System	25 Aug 2020 23:37:07
User entered 'No (N)'	System	25 Aug 2020 23:37:07

US3312197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:01:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-25T18:37:01', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '4ef657ec-1a67-4437-a272-f25b23a3e96c'	System	25 Aug 2020 23:37:07
User entered '25 Aug 2020 18:37'	System	25 Aug 2020 23:37:07

US3312197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 19:57:22

US3312197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 19:57:22

US3312197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
Data entry locked.	System	20 Aug 2020 19:57:22
User entered 'Day 7'	System	20 Aug 2020 19:57:22

US3312197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:01:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-26T18:46:36', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '497f7c28-53ae-475b-8d4d-5946ccc1ee59'	System	26 Aug 2020 23:46:52
User entered 'Yes (Y)'	System	26 Aug 2020 23:46:52

US3312197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:01:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-26T18:46:41', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '497f7c28-53ae-475b-8d4d-5946ccc1ee59' User entered '98.6'	System	26 Aug 2020 23:46:52
	System	26 Aug 2020 23:46:52

US3312197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-26T18:46:45', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '497f7c28-53ae-475b-8d4d-5946ccc1ee59'	System	26 Aug 2020 23:46:52
User entered 'No (N)'	System	26 Aug 2020 23:46:52

US3312197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:01:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-26T18:46:50', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '497f7c28-53ae-475b-8d4d-5946ccc1ee59'	System	26 Aug 2020 23:46:52
User entered '26 Aug 2020 18:46'	System	26 Aug 2020 23:46:52

US3312197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 19:57:22

US3312197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 19:57:22

US3312197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
Data entry locked.	System	20 Aug 2020 19:57:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 19:57:22

US3312197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:01:02

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 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-20T15:17:39', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '74d6de46-e6c2-4a0e-b281-d334f16e1fbf'	System	20 Aug 2020 20:17:57
User entered 'None (1)'	System	20 Aug 2020 20:17:57

US3312197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:01:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-20T15:17:42', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '74d6de46-e6c2-4a0e-b281-d334f16e1fbf' User entered 'No (N)'	System	20 Aug 2020 20:17:57
	System	20 Aug 2020 20:17:57

US3312197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-20T15:17:45', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '74d6de46-e6c2-4a0e-b281-d334f16e1fbf' User entered 'No (N)'	System	20 Aug 2020 20:17:57
	System	20 Aug 2020 20:17:57

US3312197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:01:02

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 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-20T15:17:48', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '74d6de46-e6c2-4a0e-b281-d334f16e1fbf'	System	20 Aug 2020 20:17:57
User entered 'None (1)'	System	20 Aug 2020 20:17:57

US3312197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:01:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-20T15:17:54', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '74d6de46-e6c2-4a0e-b281-d334f16e1fbf' User entered '20 Aug 2020 15:17'	System	20 Aug 2020 20:17:57
	System	20 Aug 2020 20:17:57

US3312197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
User entered '20 Aug 2020 15:09'	System	20 Aug 2020 19:57:22

US3312197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
User entered '20 Aug 2020 17:39'	System	20 Aug 2020 19:57:22

US3312197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
Data entry locked.	System	20 Aug 2020 19:57:22
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 19:57:22

US3312197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:01:02

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 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-20T18:35:08', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '5e9459d8-48e3-4bf2-94c7-f2320bc22156' User entered 'None (1)'	System	20 Aug 2020 23:35:28
	System	20 Aug 2020 23:35:28

US3312197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:01:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-20T18:35:12', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '5e9459d8-48e3-4bf2-94c7-f2320bc22156'	System	20 Aug 2020 23:35:28
User entered 'No (N)'	System	20 Aug 2020 23:35:28

US3312197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-20T18:35:16', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '5e9459d8-48e3-4bf2-94c7-f2320bc22156' User entered 'No (N)'	System	20 Aug 2020 23:35:28
	System	20 Aug 2020 23:35:28

US3312197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:01:02

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 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-20T18:35:21', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '5e9459d8-48e3-4bf2-94c7-f2320bc22156'	System	20 Aug 2020 23:35:28
User entered 'None (1)'	System	20 Aug 2020 23:35:28

US3312197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:01:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-20T18:35:26', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '5e9459d8-48e3-4bf2-94c7-f2320bc22156'	System	20 Aug 2020 23:35:28
User entered '20 Aug 2020 18:35'	System	20 Aug 2020 23:35:28

US3312197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
User entered '20 Aug 2020 18:34'	System	20 Aug 2020 19:57:22

US3312197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 19:57:22

US3312197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
Data entry locked.	System	20 Aug 2020 19:57:22
User entered 'Day 2'	System	20 Aug 2020 19:57:22

US3312197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:01:02

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 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-21T14:51:57', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'a3c3a3c7-7e9f-48b8-922d-7443b81e6d0d'	System	21 Aug 2020 19:53:09
User entered 'Does not interfere with activity (2)'	System	21 Aug 2020 19:53:09

US3312197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-21T14:52:03', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'a3c3a3c7-7e9f-48b8-922d-7443b81e6d0d'	System	21 Aug 2020 19:53:09
User entered 'No (N)'	System	21 Aug 2020 19:53:09

US3312197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-21T14:52:46', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'a3c3a3c7-7e9f-48b8-922d-7443b81e6d0d' User entered 'No (N)'	System	21 Aug 2020 19:53:09
	System	21 Aug 2020 19:53:09

US3312197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:01:02

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 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-21T14:52:51', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'a3c3a3c7-7e9f-48b8-922d-7443b81e6d0d' User entered 'None (1)'	System	21 Aug 2020 19:53:09
	System	21 Aug 2020 19:53:09

US3312197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:01:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-21T14:53:05', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'a3c3a3c7-7e9f-48b8-922d-7443b81e6d0d' User entered '21 Aug 2020 14:53'	System	21 Aug 2020 19:53:09
	System	21 Aug 2020 19:53:09

US3312197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 19:57:22

US3312197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 19:57:22

US3312197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
Data entry locked.	System	20 Aug 2020 19:57:22
User entered 'Day 3'	System	20 Aug 2020 19:57:22

US3312197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:01:02

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 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-22T18:50:31', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'f1d121c3-0245-4f16-9d1f-9a6f819997ae'	System	22 Aug 2020 23:50:48
User entered 'Does not interfere with activity (2)'	System	22 Aug 2020 23:50:48

US3312197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:01:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-22T18:50:35', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'f1d121c3-0245-4f16-9d1f-9a6f819997ae'	System	22 Aug 2020 23:50:48
User entered 'No (N)'	System	22 Aug 2020 23:50:48

US3312197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-22T18:50:39', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'f1d121c3-0245-4f16-9d1f-9a6f819997ae'	System	22 Aug 2020 23:50:48
User entered 'No (N)'	System	22 Aug 2020 23:50:48

US3312197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:01:02

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 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-22T18:50:43', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'f1d121c3-0245-4f16-9d1f-9a6f819997ae'	System	22 Aug 2020 23:50:48
User entered 'None (1)'	System	22 Aug 2020 23:50:48

US3312197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:01:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-22T18:50:47', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'f1d121c3-0245-4f16-9d1f-9a6f819997ae'	System	22 Aug 2020 23:50:48
User entered '22 Aug 2020 18:50'	System	22 Aug 2020 23:50:48

US3312197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 19:57:22

US3312197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 19:57:22

US3312197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
Data entry locked.	System	20 Aug 2020 19:57:22
User entered 'Day 4'	System	20 Aug 2020 19:57:22

US3312197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:01:02

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 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-23T18:35:57', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '5f9fb478-cd54-4411-a010-ec2c05760814' User entered 'None (1)'	System	23 Aug 2020 23:36:20
	System	23 Aug 2020 23:36:20

US3312197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-23T18:36:01', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '5f9fb478-cd54-4411-a010-ec2c05760814' User entered 'No (N)'	System	23 Aug 2020 23:36:20
	System	23 Aug 2020 23:36:20

US3312197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-23T18:36:04', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '5f9fb478-cd54-4411-a010-ec2c05760814' User entered 'No (N)'	System	23 Aug 2020 23:36:20
	System	23 Aug 2020 23:36:20

US3312197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:01:02

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 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-23T18:36:08', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '5f9fb478-cd54-4411-a010-ec2c05760814' User entered 'None (1)'	System	23 Aug 2020 23:36:20
	System	23 Aug 2020 23:36:20

US3312197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:01:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-23T18:36:12', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '5f9fb478-cd54-4411-a010-ec2c05760814' User entered '23 Aug 2020 18:36'	System	23 Aug 2020 23:36:20
	System	23 Aug 2020 23:36:20

US3312197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 19:57:22

US3312197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 19:57:22

US3312197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
Data entry locked.	System	20 Aug 2020 19:57:22
User entered 'Day 5'	System	20 Aug 2020 19:57:22

US3312197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:01:02

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 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-24T21:01:22', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'f32a8c70-ce54-4625-9275-2aef90ef06e4'	System	25 Aug 2020 02:01:44
User entered 'None (1)'	System	25 Aug 2020 02:01:44

US3312197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-24T21:01:26', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'f32a8c70-ce54-4625-9275-2aef90ef06e4' User entered 'No (N)'	System	25 Aug 2020 02:01:44
	System	25 Aug 2020 02:01:44

US3312197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-24T21:01:30', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'f32a8c70-ce54-4625-9275-2aef90ef06e4'	System	25 Aug 2020 02:01:44
User entered 'No (N)'	System	25 Aug 2020 02:01:44

US3312197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:01:02

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 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-24T21:01:35', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'f32a8c70-ce54-4625-9275-2aef90ef06e4'	System	25 Aug 2020 02:01:44
User entered 'None (1)'	System	25 Aug 2020 02:01:44

US3312197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:01:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-24T21:01:39', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'f32a8c70-ce54-4625-9275-2aef90ef06e4' User entered '24 Aug 2020 21:01'	System	25 Aug 2020 02:01:44
	System	25 Aug 2020 02:01:44

US3312197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 19:57:22

US3312197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 19:57:22

US3312197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
Data entry locked.	System	20 Aug 2020 19:57:22
User entered 'Day 6'	System	20 Aug 2020 19:57:22

US3312197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:01:02

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 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-25T18:37:06', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '42d71fa8-4108-4d0e-8b95-ba4feaacad6b'	System	25 Aug 2020 23:37:21
User entered 'None (1)'	System	25 Aug 2020 23:37:21

US3312197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:01:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-25T18:37:10', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '42d71fa8-4108-4d0e-8b95-ba4fea6b'	System	25 Aug 2020 23:37:21
User entered 'No (N)'	System	25 Aug 2020 23:37:21

US3312197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-25T18:37:13', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '42d71fa8-4108-4d0e-8b95-ba4fea6b'	System	25 Aug 2020 23:37:21
User entered 'No (N)'	System	25 Aug 2020 23:37:21

US3312197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:01:02

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 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-25T18:37:16', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '42d71fa8-4108-4d0e-8b95-ba4feaacad6b'	System	25 Aug 2020 23:37:21
User entered 'None (1)'	System	25 Aug 2020 23:37:21

US3312197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:01:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-25T18:37:19', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '42d71fa8-4108-4d0e-8b95-ba4fea6ac6b'	System	25 Aug 2020 23:37:21
User entered '25 Aug 2020 18:37'	System	25 Aug 2020 23:37:21

US3312197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 19:57:22

US3312197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 19:57:22

US3312197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
Data entry locked.	System	20 Aug 2020 19:57:22
User entered 'Day 7'	System	20 Aug 2020 19:57:22

US3312197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:01:02

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 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-26T18:46:54', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '3bab8770-de1a-4446-97ce-a91a2a82f7d1' User entered 'None (1)'	System	26 Aug 2020 23:47:12
	System	26 Aug 2020 23:47:12

US3312197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:01:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-26T18:46:57', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '3bab8770-de1a-4446-97ce-a91a2a82f7d1'	System	26 Aug 2020 23:47:12
User entered 'No (N)'	System	26 Aug 2020 23:47:12

US3312197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-26T18:47:00', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '3bab8770-de1a-4446-97ce-a91a2a82f7d1' User entered 'No (N)'	System	26 Aug 2020 23:47:12
	System	26 Aug 2020 23:47:12

US3312197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:01:02

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 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-26T18:47:04', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '3bab8770-de1a-4446-97ce-a91a2a82f7d1' User entered 'None (1)'	System	26 Aug 2020 23:47:12
	System	26 Aug 2020 23:47:12

US3312197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:01:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-26T18:47:07', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '3bab8770-de1a-4446-97ce-a91a2a82f7d1' User entered '26 Aug 2020 18:47'	System	26 Aug 2020 23:47:12
	System	26 Aug 2020 23:47:12

US3312197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 19:57:22

US3312197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 19:57:22

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
Data entry locked.	System	20 Aug 2020 19:57:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 19:57:22

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:01:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-20T15:24:38', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'dc189d74-3d0d-44c5-a63c-4d21ffa4e1f3'	System	20 Aug 2020 20:25:13
User entered 'None (0)'	System	20 Aug 2020 20:25:13

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:01:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-20T15:24:40', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'dc189d74-3d0d-44c5-a63c-4d21ffa4e1f3'	System	20 Aug 2020 20:25:13
User entered 'None (0)'	System	20 Aug 2020 20:25:13

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:01:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-20T15:24:46', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'dc189d74-3d0d-44c5-a63c-4d21ffa4e1f3'	System	20 Aug 2020 20:25:13
User entered 'None (0)'	System	20 Aug 2020 20:25:13

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:01:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-20T15:24:50', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'dc189d74-3d0d-44c5-a63c-4d21ffa4e1f3'	System	20 Aug 2020 20:25:13
User entered 'None (0)'	System	20 Aug 2020 20:25:13

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:01:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-20T15:24:52', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'dc189d74-3d0d-44c5-a63c-4d21ffa4e1f3'	System	20 Aug 2020 20:25:13
User entered 'None (0)'	System	20 Aug 2020 20:25:13

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:01:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-20T15:24:54', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'dc189d74-3d0d-44c5-a63c-4d21ffa4e1f3'	System	20 Aug 2020 20:25:13
User entered 'None (0)'	System	20 Aug 2020 20:25:13

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:01:02

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 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-20T15:25:05', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'dc189d74-3d0d-44c5-a63c-4d21ffa4e1f3'	System	20 Aug 2020 20:25:13
User entered 'No (N)'	System	20 Aug 2020 20:25:13

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:01:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-20T15:25:11', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'dc189d74-3d0d-44c5-a63c-4d21ffa4e1f3'	System	20 Aug 2020 20:25:13
User entered '20 Aug 2020 15:25'	System	20 Aug 2020 20:25:13

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
User entered '20 Aug 2020 15:09'	System	20 Aug 2020 19:57:22

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
User entered '20 Aug 2020 17:39'	System	20 Aug 2020 19:57:22

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
Data entry locked.	System	20 Aug 2020 19:57:22
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 19:57:22

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:01:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-20T18:35:32', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '6290673c-2392-4438-9e9e-3bc4abd95a7e' User entered 'None (0)'	System	20 Aug 2020 23:36:08
	System	20 Aug 2020 23:36:08

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:01:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-20T18:35:35', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '6290673c-2392-4438-9e9e-3bc4abd95a7e' User entered 'None (0)'	System	20 Aug 2020 23:36:08
	System	20 Aug 2020 23:36:08

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:01:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-20T18:35:39', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '6290673c-2392-4438-9e9e-3bc4abd95a7e' User entered 'None (0)'	System	20 Aug 2020 23:36:08
	System	20 Aug 2020 23:36:08

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:01:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-20T18:35:43', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '6290673c-2392-4438-9e9e-3bc4abd95a7e' User entered 'None (0)'	System	20 Aug 2020 23:36:08
	System	20 Aug 2020 23:36:08

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:01:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-20T18:35:46', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '6290673c-2392-4438-9e9e-3bc4abd95a7e' User entered 'None (0)'	System	20 Aug 2020 23:36:08
	System	20 Aug 2020 23:36:08

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:01:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-20T18:35:49', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '6290673c-2392-4438-9e9e-3bc4abd95a7e' User entered 'None (0)'	System	20 Aug 2020 23:36:08
	System	20 Aug 2020 23:36:08

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:01:02

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 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-20T18:36:01', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '6290673c-2392-4438-9e9e-3bc4abd95a7e' User entered 'No (N)'	System	20 Aug 2020 23:36:08
	System	20 Aug 2020 23:36:08

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:01:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-20T18:36:04', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '6290673c-2392-4438-9e9e-3bc4abd95a7e' User entered '20 Aug 2020 18:36'	System	20 Aug 2020 23:36:08
	System	20 Aug 2020 23:36:08

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
User entered '20 Aug 2020 18:34'	System	20 Aug 2020 19:57:22

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 19:57:22

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
Data entry locked.	System	20 Aug 2020 19:57:22
User entered 'Day 2'	System	20 Aug 2020 19:57:22

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:01:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-21T14:53:12', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'd3e2cbfa-3ad0-4fb0-af63-12675a8c398c' User entered 'None (0)'	System	21 Aug 2020 19:53:56
	System	21 Aug 2020 19:53:56

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:01:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-21T14:53:16', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'd3e2cbfa-3ad0-4fb0-af63-12675a8c398c' User entered 'None (0)'	System	21 Aug 2020 19:53:56
	System	21 Aug 2020 19:53:56

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:01:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-21T14:53:20', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'd3e2cbfa-3ad0-4fb0-af63-12675a8c398c' User entered 'None (0)'	System	21 Aug 2020 19:53:56
	System	21 Aug 2020 19:53:56

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:01:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-21T14:53:28', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'd3e2cbfa-3ad0-4fb0-af63-12675a8c398c' User entered 'None (0)'	System	21 Aug 2020 19:53:56
	System	21 Aug 2020 19:53:56

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:01:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-21T14:53:31', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'd3e2cbfa-3ad0-4fb0-af63-12675a8c398c' User entered 'None (0)'	System	21 Aug 2020 19:53:56
	System	21 Aug 2020 19:53:56

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:01:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-21T14:53:35', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'd3e2cbfa-3ad0-4fb0-af63-12675a8c398c' User entered 'None (0)'	System	21 Aug 2020 19:53:56
	System	21 Aug 2020 19:53:56

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:01:02

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 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-21T14:53:49', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'd3e2cbfa-3ad0-4fb0-af63-12675a8c398c'	System	21 Aug 2020 19:53:56
User entered 'No (N)'	System	21 Aug 2020 19:53:56

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:01:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-21T14:53:54', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'd3e2cbfa-3ad0-4fb0-af63-12675a8c398c' User entered '21 Aug 2020 14:53'	System	21 Aug 2020 19:53:56
	System	21 Aug 2020 19:53:56

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 19:57:22

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 19:57:22

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
Data entry locked.	System	20 Aug 2020 19:57:22
User entered 'Day 3'	System	20 Aug 2020 19:57:22

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:01:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-22T18:50:52', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '58e108bd-0330-402a-a2be-0552510c60af' User entered 'None (0)'	System	22 Aug 2020 23:51:51
	System	22 Aug 2020 23:51:51

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:01:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-22T18:50:58', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '58e108bd-0330-402a-a2be-0552510c60af' User entered 'None (0)'	System	22 Aug 2020 23:51:51
	System	22 Aug 2020 23:51:51

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:01:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-22T18:51:03', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '58e108bd-0330-402a-a2be-0552510c60af' User entered 'None (0)'	System	22 Aug 2020 23:51:51
	System	22 Aug 2020 23:51:51

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:01:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-22T18:51:07', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '58e108bd-0330-402a-a2be-0552510c60af' User entered 'None (0)'	System	22 Aug 2020 23:51:51
	System	22 Aug 2020 23:51:51

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:01:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-22T18:51:10', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '58e108bd-0330-402a-a2be-0552510c60af' User entered 'None (0)'	System	22 Aug 2020 23:51:51
	System	22 Aug 2020 23:51:51

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:01:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-22T18:51:13', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '58e108bd-0330-402a-a2be-0552510c60af' User entered 'None (0)'	System	22 Aug 2020 23:51:51
	System	22 Aug 2020 23:51:51

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:01:02

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 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-22T18:51:21', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '58e108bd-0330-402a-a2be-0552510c60af' User entered 'No (N)'	System	22 Aug 2020 23:51:51
	System	22 Aug 2020 23:51:51

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:01:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-22T18:51:25', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '58e108bd-0330-402a-a2be-0552510c60af' User entered '22 Aug 2020 18:51'	System	22 Aug 2020 23:51:51
	System	22 Aug 2020 23:51:51

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 19:57:22

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 19:57:22

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
Data entry locked.	System	20 Aug 2020 19:57:22
User entered 'Day 4'	System	20 Aug 2020 19:57:22

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:01:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-23T18:36:17', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '2f8aaed6-86cf-47ad-aa51-171979f78289' User entered 'None (0)'	System	23 Aug 2020 23:36:55
	System	23 Aug 2020 23:36:55

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:01:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-23T18:36:22', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '2f8aaed6-86cf-47ad-aa51-171979f78289' User entered 'None (0)'	System	23 Aug 2020 23:36:55
	System	23 Aug 2020 23:36:55

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:01:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-23T18:36:26', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '2f8aaed6-86cf-47ad-aa51-171979f78289' User entered 'None (0)'	System	23 Aug 2020 23:36:55
	System	23 Aug 2020 23:36:55

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:01:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-23T18:36:31', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '2f8aaed6-86cf-47ad-aa51-171979f78289' User entered 'None (0)'	System	23 Aug 2020 23:36:55
	System	23 Aug 2020 23:36:55

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:01:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-23T18:36:34', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '2f8aaed6-86cf-47ad-aa51-171979f78289' User entered 'None (0)'	System	23 Aug 2020 23:36:55
	System	23 Aug 2020 23:36:55

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:01:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-23T18:36:37', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '2f8aaed6-86cf-47ad-aa51-171979f78289' User entered 'None (0)'	System	23 Aug 2020 23:36:55
	System	23 Aug 2020 23:36:55

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:01:02

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 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-23T18:36:48', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '2f8aaed6-86cf-47ad-aa51-171979f78289' User entered 'No (N)'	System	23 Aug 2020 23:36:55
	System	23 Aug 2020 23:36:55

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:01:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-23T18:36:52', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '2f8aaed6-86cf-47ad-aa51-171979f78289'	System	23 Aug 2020 23:36:55
User entered '23 Aug 2020 18:36'	System	23 Aug 2020 23:36:55

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 19:57:22

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 19:57:22

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
Data entry locked.	System	20 Aug 2020 19:57:22
User entered 'Day 5'	System	20 Aug 2020 19:57:22

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:01:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-24T21:01:44', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'a591b822-3783-4e2a-ae8a-4faceff7780' User entered 'None (0)'	System	25 Aug 2020 02:02:22
	System	25 Aug 2020 02:02:22

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:01:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-24T21:01:55', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'a591b822-3783-4e2a-ae8a-4faceff7780' User entered 'None (0)'	System	25 Aug 2020 02:02:22
	System	25 Aug 2020 02:02:22

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:01:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-24T21:01:59', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'a591b822-3783-4e2a-ae8a-4faceff7780' User entered 'None (0)'	System	25 Aug 2020 02:02:22
	System	25 Aug 2020 02:02:22

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:01:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-24T21:02:03', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'a591b822-3783-4e2a-ae8a-4faceff7780' User entered 'None (0)'	System	25 Aug 2020 02:02:22
	System	25 Aug 2020 02:02:22

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:01:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-24T21:02:06', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'a591b822-3783-4e2a-ae8a-4faceff7780' User entered 'None (0)'	System	25 Aug 2020 02:02:22
	System	25 Aug 2020 02:02:22

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:01:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-24T21:02:09', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'a591b822-3783-4e2a-ae8a-4faceff7780' User entered 'None (0)'	System	25 Aug 2020 02:02:22
	System	25 Aug 2020 02:02:22

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:01:02

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 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-24T21:02:16', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'a591b822-3783-4e2a-ae8a-4faceff7780' User entered 'No (N)'	System	25 Aug 2020 02:02:22
	System	25 Aug 2020 02:02:22

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:01:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-24T21:02:20', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'a591b822-3783-4e2a-ae8a-4faceff7780' User entered '24 Aug 2020 21:02'	System	25 Aug 2020 02:02:22
	System	25 Aug 2020 02:02:22

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 19:57:22

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 19:57:22

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
Data entry locked.	System	20 Aug 2020 19:57:22
User entered 'Day 6'	System	20 Aug 2020 19:57:22

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:01:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-25T18:37:25', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '96287e39-1aa6-4e48-922b-69c524e5b339' User entered 'None (0)'	System	25 Aug 2020 23:38:17
	System	25 Aug 2020 23:38:17

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:01:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-25T18:37:30', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '96287e39-1aa6-4e48-922b-69c524e5b339'	System	25 Aug 2020 23:38:17
User entered 'No interference with activity (1)'	System	25 Aug 2020 23:38:17

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:01:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-25T18:37:34', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '96287e39-1aa6-4e48-922b-69c524e5b339' User entered 'None (0)'	System	25 Aug 2020 23:38:17
	System	25 Aug 2020 23:38:17

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:01:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-25T18:37:38', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '96287e39-1aa6-4e48-922b-69c524e5b339'	System	25 Aug 2020 23:38:17
User entered 'No interference with activity (1)'	System	25 Aug 2020 23:38:17

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:01:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-25T18:37:41', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '96287e39-1aa6-4e48-922b-69c524e5b339' User entered 'None (0)'	System	25 Aug 2020 23:38:17
	System	25 Aug 2020 23:38:17

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:01:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-25T18:37:43', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '96287e39-1aa6-4e48-922b-69c524e5b339' User entered 'None (0)'	System	25 Aug 2020 23:38:17
	System	25 Aug 2020 23:38:17

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:01:02

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 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-25T18:38:00', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '96287e39-1aa6-4e48-922b-69c524e5b339'	System	25 Aug 2020 23:38:17
User entered 'Yes (Y)'	System	25 Aug 2020 23:38:17

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:01:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-25T18:38:14', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '96287e39-1aa6-4e48-922b-69c524e5b339'	System	25 Aug 2020 23:38:17
User entered '25 Aug 2020 18:38'	System	25 Aug 2020 23:38:17

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 19:57:22

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 19:57:22

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
Data entry locked.	System	20 Aug 2020 19:57:22
User entered 'Day 7'	System	20 Aug 2020 19:57:22

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:01:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-26T18:47:12', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '249fdefe-0f9c-4aa2-a4a1-dab85d449686' User entered 'None (0)'	System	26 Aug 2020 23:47:42
	System	26 Aug 2020 23:47:42

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:01:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-26T18:47:14', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '249fdefe-0f9c-4aa2-a4a1-dab85d449686'	System	26 Aug 2020 23:47:42
User entered 'None (0)'	System	26 Aug 2020 23:47:42

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:01:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-26T18:47:19', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '249fdefe-0f9c-4aa2-a4a1-dab85d449686' User entered 'None (0)'	System	26 Aug 2020 23:47:42
	System	26 Aug 2020 23:47:42

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:01:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-26T18:47:22', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '249fdefe-0f9c-4aa2-a4a1-dab85d449686'	System	26 Aug 2020 23:47:42
User entered 'None (0)'	System	26 Aug 2020 23:47:42

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:01:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-26T18:47:25', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '249fdefe-0f9c-4aa2-a4a1-dab85d449686' User entered 'None (0)'	System	26 Aug 2020 23:47:42
	System	26 Aug 2020 23:47:42

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:01:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-26T18:47:27', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '249fdefe-0f9c-4aa2-a4a1-dab85d449686' User entered 'None (0)'	System	26 Aug 2020 23:47:42
	System	26 Aug 2020 23:47:42

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:01:02

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 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-26T18:47:34', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '249fdefe-0f9c-4aa2-a4a1-dab85d449686'	System	26 Aug 2020 23:47:42
User entered 'No (N)'	System	26 Aug 2020 23:47:42

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:01:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-08-26T18:47:36', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '249fdefe-0f9c-4aa2-a4a1-dab85d449686' User entered '26 Aug 2020 18:47'	System	26 Aug 2020 23:47:42
	System	26 Aug 2020 23:47:42

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 19:57:22

US3312197

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 19:57:22

US3312197

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:43:30

US3312197

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '27 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:43:30

US3312197

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:43:30

US3312197

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered empty.	(b) (4)	28 Aug 2020 18:43:30
	Karol Moore (b) (4)	
	(b) (4)	

US3312197

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:43:33

US3312197

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User entered 'I'	System	28 Aug 2020 18:43:33

US3312197

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:16
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	04 Sep 2020 16:35:15

US3312197

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:16
User entered '3 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	04 Sep 2020 16:35:15

US3312197

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:16
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karol Moore (b) (4) (b) (4)	04 Sep 2020 16:35:15

US3312197

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:16
User entered empty.	(b) (4)	04 Sep 2020 16:35:15
	Karol Moore (b) (4)	
	(b) (4)	

US3312197

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:16
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	04 Sep 2020 16:35:19

US3312197

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:30:51
User entered 'I'	System	04 Sep 2020 16:35:19

US3312197

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:05
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 20:51:34

US3312197

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:05
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '10 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Sep 2020 20:51:34

US3312197

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:05
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karol Moore (b) (4)	10 Sep 2020 20:51:34

US3312197

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:05
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered empty.	(b) (4) Karol Moore (b) (4)	10 Sep 2020 20:51:34
	(b) (4)	

US3312197

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:05
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:16
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	10 Sep 2020 20:51:37

US3312197

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:05
User entered 'I'	System	10 Sep 2020 20:51:37

US3312197

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:01:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Sep 2020 00:19:56

US3312197

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '17 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Sep 2020 00:19:56

US3312197

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:01:02

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'Clinic (Clinic)'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Sep 2020 00:19:56

US3312197

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:01:02

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User entered 'VISIT2'	System	19 Sep 2020 00:19:56

US3312197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:02

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User accepted default value 'Pre-Dose (PREDOSE)'	Karol Moore (b) (4) (b) (4)	19 Sep 2020 00:20:34

US3312197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Sep 2020 00:20:34

US3312197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '17 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Sep 2020 00:20:34

US3312197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '10:01'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Sep 2020 00:20:34

US3312197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:02

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User entered '17 Sep 2020 10:01'	System	19 Sep 2020 00:20:34

US3312197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '98.4' F	(b) (4) Karol Moore (b) (4)	19 Sep 2020 00:20:34

US3312197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Sep 2020 00:20:34

US3312197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	19 Sep 2020 00:20:34

US3312197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Sep 2020 00:21:04
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	19 Sep 2020 00:21:04
User entered '70' reason for change: Data Entry Error	Karol Moore (b) (4)	19 Sep 2020 00:21:04
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Sep 2020 00:20:34
User entered empty.	Karol Moore (b) (4)	19 Sep 2020 00:20:34
	(b) (4)	

US3312197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User entered 'bpm'	System	19 Sep 2020 00:21:04
User entered empty.	System	19 Sep 2020 00:20:34

US3312197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:02

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Sep 2020 00:21:04
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	19 Sep 2020 00:21:04
User entered '16' reason for change: Data Entry Error	Karol Moore (b) (4)	19 Sep 2020 00:21:04
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Sep 2020 00:20:34
User entered empty.	Karol Moore (b) (4)	19 Sep 2020 00:20:34
	(b) (4)	

US3312197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User entered 'breaths/min'	System	19 Sep 2020 00:21:04
User entered empty.	System	19 Sep 2020 00:20:34

US3312197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Sep 2020 00:21:04
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	19 Sep 2020 00:21:04
User entered '131' reason for change: Data Entry Error	Karol Moore (b) (4)	19 Sep 2020 00:21:04
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Sep 2020 00:20:34
User entered empty.	Karol Moore (b) (4)	19 Sep 2020 00:20:34
	(b) (4)	

US3312197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User entered 'mmHg'	System	19 Sep 2020 00:21:04
User entered empty.	System	19 Sep 2020 00:20:34

US3312197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Sep 2020 00:21:04
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	19 Sep 2020 00:21:04
User entered '66' reason for change: Data Entry Error	Karol Moore (b) (4)	19 Sep 2020 00:21:04
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Sep 2020 00:20:34
User entered empty.	Karol Moore (b) (4)	19 Sep 2020 00:20:34
	(b) (4)	

US3312197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:02

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User entered 'mmHg'	System	19 Sep 2020 00:21:04
User entered empty.	System	19 Sep 2020 00:20:34

US3312197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:02

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User accepted default value 'Post-Dose (POSTDOSE)'	Karol Moore (b) (4) (b) (4)	19 Sep 2020 00:20:34

US3312197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User closed query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	(b) (4)	19 Sep 2020 00:20:46
User opened query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	System	19 Sep 2020 00:20:34
User entered 'No (N)'	Karol Moore (b) (4)	19 Sep 2020 00:20:34
	(b) (4)	

US3312197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	19 Sep 2020 00:20:34

US3312197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	19 Sep 2020 00:20:34

US3312197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:02

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User entered empty.	System	19 Sep 2020 00:20:34

US3312197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	19 Sep 2020 00:20:34

US3312197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered empty; reason for change Data Entry Error	(b) (4)	19 Sep 2020 00:20:46
User entered 'Oral (Oral)'	Karol Moore (b) (4)	19 Sep 2020 00:20:34
	(b) (4)	

US3312197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered empty.	(b) (4) Karol Moore (b) (4)	19 Sep 2020 00:20:34

US3312197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	19 Sep 2020 00:20:34

US3312197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User entered empty.	System	19 Sep 2020 00:20:34

US3312197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:02

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	19 Sep 2020 00:20:34

US3312197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User entered empty.	System	19 Sep 2020 00:20:34

US3312197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	19 Sep 2020 00:20:34

US3312197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User entered empty.	System	19 Sep 2020 00:20:34

US3312197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	19 Sep 2020 00:20:34

US3312197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:02

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User entered empty.	System	19 Sep 2020 00:20:34

US3312197

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:01:02

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Sep 2020 00:21:16

US3312197

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:01:02

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '17 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Sep 2020 00:21:16

US3312197

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:01:02

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'No (N)'	(b) (4)	19 Sep 2020 00:22:31
	Karol Moore (b) (4)	
	(b) (4)	

US3312197

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:01:02

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'Physician withheld dose due to Adverse Event (PHYSICIAN AE)'	Karol Moore (b) (4)	19 Sep 2020 00:22:31

US3312197

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:01:02

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 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User closed query 'Per CDM: per pg 27 of CCGs please specify since reason is Physician Decision. Consider adding specific AE. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Oct 2020 11:24:30
Query 'Per CDM: per pg 27 of CCGs please specify since reason is Physician Decision. Consider adding specific AE. Thank you. ' answered with 'Updated. Thanks. ' (Site from DM).	Heather Barker (b) (4) (b) (4)	22 Oct 2020 23:23:14
User entered 'EXACERBATION OF LEFT CERVICAL RADICULOPATHY' reason for change: Data Entry Error	Heather Barker (b) (4) (b) (4)	22 Oct 2020 23:23:03
User opened query 'Per CDM: per pg 27 of CCGs please specify since reason is Physician Decision. Consider adding specific AE. Thank you. ' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 14:40:34
User entered empty.	Karol Moore (b) (4) (b) (4)	19 Sep 2020 00:22:31

US3312197

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:01:02

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User entered empty.	System	19 Sep 2020 00:22:31

US3312197

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:01:02

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered empty.	(b) (4) Karol Moore (b) (4)	19 Sep 2020 00:22:31

US3312197

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:01:02

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered empty.	(b) (4) Karol Moore (b) (4)	19 Sep 2020 00:22:31

US3312197

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:01:02

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User entered empty.	System	19 Sep 2020 00:22:31

US3312197

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:01:02

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	19 Sep 2020 00:22:31

US3312197

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:01:02

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User entered empty.	System	19 Sep 2020 00:22:31

US3312197

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:01:02

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User entered empty.	System	19 Sep 2020 00:22:31

US3312197

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:01:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	19 Sep 2020 00:22:43

US3312197

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:01:02

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '17 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Sep 2020 00:22:43

US3312197

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:01:02

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '11:01'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Sep 2020 00:22:43

US3312197

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:01:02

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User entered '17 Sep 2020 11:01'	System	19 Sep 2020 00:22:43

US3312197

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:01:02

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '17 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Sep 2020 00:22:55

US3312197

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:01:02

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Karol Moore (b) (4) (b) (4)	19 Sep 2020 00:22:55

US3312197

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:01:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Sep 2020 00:22:55

US3312197

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:01:02

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '10:54'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Sep 2020 00:22:55

US3312197

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:01:02

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User entered '17 Sep 2020 10:54'	System	19 Sep 2020 00:22:55

US3312197

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:01:02

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Karol Moore (b) (4) (b) (4)	19 Sep 2020 00:22:55

US3312197

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:01:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	19 Sep 2020 00:22:55

US3312197

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:01:02

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	19 Sep 2020 00:22:55

US3312197

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:01:02

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User entered empty.	System	19 Sep 2020 00:22:55

US3312197

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	19 Sep 2020 00:23:02

US3312197

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User entered 'I'	System	19 Sep 2020 00:23:02

US3312197

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:31:07

US3312197

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '24 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:31:07

US3312197

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:31:07

US3312197

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered empty.	(b) (4)	06 Oct 2020 18:31:07
	Karol Moore (b) (4)	
	(b) (4)	

US3312197

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:31:10

US3312197

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User entered 'I'	System	06 Oct 2020 18:31:10

US3312197

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:31:34

US3312197

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:02

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '1 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:31:34

US3312197

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:31:34

US3312197

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered empty.	(b) (4)	06 Oct 2020 18:31:34
	Karol Moore (b) (4)	
	(b) (4)	

US3312197

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:31:37

US3312197

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User entered 'I'	System	06 Oct 2020 18:31:37

US3312197

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 13:36:28

US3312197

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:02

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '8 Oct 2020'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 13:36:28

US3312197

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 13:36:28

US3312197

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 13:36:28

US3312197

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 13:36:07

US3312197

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User entered 'I'	System	09 Oct 2020 13:36:07

US3312197

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:01:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 19:44:55

US3312197

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '12 Oct 2020'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 19:44:55

US3312197

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:01:02

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 19:44:55

US3312197

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:01:02

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User entered 'VISIT3'	System	20 Oct 2020 19:44:55

US3312197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 19:45:28

US3312197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '12 Oct 2020'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 19:45:28

US3312197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '08:33'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 19:45:28

US3312197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User entered '12 Oct 2020 08:33'	System	20 Oct 2020 19:45:28

US3312197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '97.6' F	(b) (4) (b) (4), (b) (6)	20 Oct 2020 19:45:28

US3312197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 19:45:28

US3312197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 19:45:28

US3312197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '80'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 19:45:28

US3312197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User entered 'bpm'	System	20 Oct 2020 19:45:28

US3312197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '16'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 19:45:28

US3312197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User entered 'breaths/min'	System	20 Oct 2020 19:45:28

US3312197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4)	20 Oct 2020 19:45:51
Query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	20 Oct 2020 19:45:51
User entered '123' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Oct 2020 19:45:51
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	20 Oct 2020 19:45:28
User entered '61'	(b) (4), (b) (6)	20 Oct 2020 19:45:28

US3312197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User entered 'mmHg'	System	20 Oct 2020 19:45:28

US3312197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4)	20 Oct 2020 19:45:51
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	20 Oct 2020 19:45:51
User closed query 'Diastolic blood pressure is greater than Systolic blood pressure. Please correct.' (Site from System).	System	20 Oct 2020 19:45:51
Query 'Diastolic blood pressure is greater than Systolic blood pressure. Please correct.' answered by data change (Site from System).	System	20 Oct 2020 19:45:51
User closed query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	20 Oct 2020 19:45:51
Query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	20 Oct 2020 19:45:51
User entered '61' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Oct 2020 19:45:51
User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	20 Oct 2020 19:45:28
User opened query 'Diastolic blood pressure is greater than Systolic blood pressure. Please correct.' (Site from System).	System	20 Oct 2020 19:45:28
User opened query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	20 Oct 2020 19:45:28
User entered '123'	(b) (4), (b) (6)	20 Oct 2020 19:45:28

US3312197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User entered 'mmHg'	System	20 Oct 2020 19:45:28

US3312197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45

US3312197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45

US3312197

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:01:02

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	20 Oct 2020 19:46:11
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 19:45:56

US3312197

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:01:02

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '12 Oct 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	20 Oct 2020 19:46:11
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 19:45:56

US3312197

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:01:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 19:46:23

US3312197

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:01:02

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '12 Oct 2020'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 19:46:23

US3312197

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:01:02

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered '09:03'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 19:46:23

US3312197

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:01:02

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User entered '12 Oct 2020 09:03'	System	20 Oct 2020 19:46:23

US3312197

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:06:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 19:46:26

US3312197

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User entered 'I'	System	20 Oct 2020 19:46:26

US3312197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
Data entry locked.	System	20 Aug 2020 19:57:22
User entered 'Day 64'	System	20 Aug 2020 19:57:22

US3312197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[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 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-10-20T12:29:51', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'f838a87a-9156-495b-a596-6ce728eaba86'	System	20 Oct 2020 17:30:21
User entered 'No (N)'	System	20 Oct 2020 17:30:21

US3312197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

Have you been exposed to someone with 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 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-10-20T12:29:57', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'f838a87a-9156-495b-a596-6ce728eaba86'	System	20 Oct 2020 17:30:21
User entered 'No (N)'	System	20 Oct 2020 17:30:21

US3312197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-10-20T12:30:19', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'f838a87a-9156-495b-a596-6ce728eaba86' User entered '20 Oct 2020 12:30:19'	System	20 Oct 2020 17:30:21
	System	20 Oct 2020 17:30:21

US3312197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
Data entry locked.	System	20 Aug 2020 19:57:22
User entered '20 Oct 2020 00:01'	System	20 Aug 2020 19:57:22

US3312197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
Data entry locked.	System	20 Aug 2020 19:57:22
User entered '24 Oct 2020 23:59'	System	20 Aug 2020 19:57:22

US3312197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
Data entry locked.	System	20 Aug 2020 19:57:22
User entered 'Day 71'	System	20 Aug 2020 19:57:22

US3312197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-10-27T10:37:17', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '953e1155-46f1-4a4d-b6cd-34641a57e0f7'	System	27 Oct 2020 15:37:36
User entered 'No (N)'	System	27 Oct 2020 15:37:36

US3312197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

Have you been exposed to someone with 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 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-10-27T10:37:21', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '953e1155-46f1-4a4d-b6cd-34641a57e0f7'	System	27 Oct 2020 15:37:36
User entered 'No (N)'	System	27 Oct 2020 15:37:36

US3312197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-10-27T10:37:29', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '953e1155-46f1-4a4d-b6cd-34641a57e0f7' User entered '27 Oct 2020 10:37:29'	System	27 Oct 2020 15:37:36
	System	27 Oct 2020 15:37:36

US3312197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
Data entry locked.	System	20 Aug 2020 19:57:22
User entered '27 Oct 2020 00:01'	System	20 Aug 2020 19:57:22

US3312197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
Data entry locked.	System	20 Aug 2020 19:57:22
User entered '31 Oct 2020 23:59'	System	20 Aug 2020 19:57:22

US3312197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
Data entry locked.	System	20 Aug 2020 19:57:22
User entered 'Day 78'	System	20 Aug 2020 19:57:22

US3312197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-11-04T16:20:13', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '9b422a8e-83a4-4758-84f7-d47f47e8bcd2'	System	04 Nov 2020 22:20:34
User entered 'No (N)'	System	04 Nov 2020 22:20:34

US3312197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

Have you been exposed to someone with 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 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-11-04T16:20:26', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '9b422a8e-83a4-4758-84f7-d47f47e8bcd2'	System	04 Nov 2020 22:20:34
User entered 'No (N)'	System	04 Nov 2020 22:20:34

US3312197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-11-04T16:20:32', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '9b422a8e-83a4-4758-84f7-d47f47e8bcd2' User entered '04 Nov 2020 16:20:32'	System	04 Nov 2020 22:20:34
	System	04 Nov 2020 22:20:34

US3312197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
Data entry locked.	System	20 Aug 2020 19:57:22
User entered '03 Nov 2020 00:01'	System	20 Aug 2020 19:57:22

US3312197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
Data entry locked.	System	20 Aug 2020 19:57:22
User entered '07 Nov 2020 23:59'	System	20 Aug 2020 19:57:22

US3312197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
Data entry locked.	System	20 Aug 2020 19:57:22
User entered 'Day 92'	System	20 Aug 2020 19:57:22

US3312197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[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 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-11-17T08:37:53', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'e798c4f4-fe07-4bd5-a3ca-ac8adb0dd7a6'	System	17 Nov 2020 14:38:38
User entered 'No (N)'	System	17 Nov 2020 14:38:38

US3312197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Have you been exposed to someone with 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 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-11-17T08:38:25', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'e798c4f4-fe07-4bd5-a3ca-ac8adb0dd7a6'	System	17 Nov 2020 14:38:38
User entered 'No (N)'	System	17 Nov 2020 14:38:38

US3312197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-11-17T08:38:31', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'e798c4f4-fe07-4bd5-a3ca-ac8adb0dd7a6' User entered '17 Nov 2020 08:38:31'	System	17 Nov 2020 14:38:38
	System	17 Nov 2020 14:38:38

US3312197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
Data entry locked.	System	20 Aug 2020 19:57:22
User entered '17 Nov 2020 00:01'	System	20 Aug 2020 19:57:22

US3312197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 17:50:18
Data entry locked.	System	20 Aug 2020 19:57:22
User entered '21 Nov 2020 23:59'	System	20 Aug 2020 19:57:22

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[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 (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-11-23T17:36:29', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'a945b69e-518e-4894-b1ef-5774b72ff154'	System	23 Nov 2020 23:38:41
User entered 'Yes (Y)'	System	23 Nov 2020 23:38:41

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

Have you been exposed to someone with 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 (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-11-23T17:37:11', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'a945b69e-518e-4894-b1ef-5774b72ff154'	System	23 Nov 2020 23:38:41
User entered 'No (N)'	System	23 Nov 2020 23:38:41

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-11-23T17:37:19', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'a945b69e-518e-4894-b1ef-5774b72ff154'	System	23 Nov 2020 23:38:41
User entered 'Yes (Y)'	System	23 Nov 2020 23:38:41

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-11-23T17:37:44', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'a945b69e-518e-4894-b1ef-5774b72ff154' User entered '0'	System	23 Nov 2020 23:38:41

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-11-23T17:37:44', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'a945b69e-518e-4894-b1ef-5774b72ff154' User entered '0'	System	23 Nov 2020 23:38:41

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-11-23T17:37:44', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'a945b69e-518e-4894-b1ef-5774b72ff154' User entered '1'	System	23 Nov 2020 23:38:41

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-11-23T17:37:44', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'a945b69e-518e-4894-b1ef-5774b72ff154' User entered '1'	System	23 Nov 2020 23:38:41

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-11-23T17:37:44', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'a945b69e-518e-4894-b1ef-5774b72ff154' User entered '0'	System	23 Nov 2020 23:38:41

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-11-23T17:37:44', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'a945b69e-518e-4894-b1ef-5774b72ff154' User entered '1'	System	23 Nov 2020 23:38:41

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-11-23T17:37:44', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'a945b69e-518e-4894-b1ef-5774b72ff154' User entered '0'	System	23 Nov 2020 23:38:41

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-11-23T17:37:44', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'a945b69e-518e-4894-b1ef-5774b72ff154' User entered '0'	System	23 Nov 2020 23:38:41
	System	23 Nov 2020 23:38:41

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-11-23T17:37:44', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'a945b69e-518e-4894-b1ef-5774b72ff154' User entered '1'	System	23 Nov 2020 23:38:41

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-11-23T17:37:44', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'a945b69e-518e-4894-b1ef-5774b72ff154' User entered '0'	System	23 Nov 2020 23:38:41

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-11-23T17:37:44', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'a945b69e-518e-4894-b1ef-5774b72ff154' User entered '0'	System	23 Nov 2020 23:38:41

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-11-23T17:37:44', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'a945b69e-518e-4894-b1ef-5774b72ff154' User entered '1'	System	23 Nov 2020 23:38:41

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-11-23T17:37:44', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'a945b69e-518e-4894-b1ef-5774b72ff154' User entered '1'	System	23 Nov 2020 23:38:41

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-11-23T17:37:44', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'a945b69e-518e-4894-b1ef-5774b72ff154' User entered '1'	System	23 Nov 2020 23:38:41

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-11-23T17:37:44', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'a945b69e-518e-4894-b1ef-5774b72ff154' User entered '0'	System	23 Nov 2020 23:38:41

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-11-23T17:37:44', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'a945b69e-518e-4894-b1ef-5774b72ff154' User entered '0'	System	23 Nov 2020 23:38:41

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-11-23T17:37:44', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'a945b69e-518e-4894-b1ef-5774b72ff154' User entered '1'	System	23 Nov 2020 23:38:41

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Please 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 (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-11-23T17:38:10', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'a945b69e-518e-4894-b1ef-5774b72ff154'	System	23 Nov 2020 23:38:41
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	23 Nov 2020 23:38:41

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-11-23T17:38:24', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'a945b69e-518e-4894-b1ef-5774b72ff154'	System	23 Nov 2020 23:38:41
User entered 'No (N)'	System	23 Nov 2020 23:38:41

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-11-23T17:38:32', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'a945b69e-518e-4894-b1ef-5774b72ff154' User entered '23 Nov 2020 17:38:32'	System	23 Nov 2020 23:38:41
	System	23 Nov 2020 23:38:41

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '21 Nov 2020 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '25 Nov 2020 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[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 (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-11-30T12:47:07', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '2ca7fcdb-ff47-43e9-b3a5-29678a5cdf9e' User entered 'No (N)'	System	30 Nov 2020 18:47:26

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

Have you been exposed to someone with 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 (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-11-30T12:47:16', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '2ca7fcdb-ff47-43e9-b3a5-29678a5cdf9e'	System	30 Nov 2020 18:47:26
User entered 'No (N)'	System	30 Nov 2020 18:47:26

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-11-30T12:47:23', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '2ca7fcdb-ff47-43e9-b3a5-29678a5cdf9e' User entered '30 Nov 2020 12:47:23'	System	30 Nov 2020 18:47:26
	System	30 Nov 2020 18:47:26

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[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 (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-12-05T07:31:52', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '8ec7f189-126b-46a1-b851-f382909af94b' User entered 'No (N)'	System	05 Dec 2020 13:32:01

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Have you been exposed to someone with 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 (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-12-05T07:31:48', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '8ec7f189-126b-46a1-b851-f382909af94b' User entered 'No (N)'	System	05 Dec 2020 13:32:01

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-12-05T07:31:57', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '8ec7f189-126b-46a1-b851-f382909af94b' User entered '05 Dec 2020 07:31:57'	System	05 Dec 2020 13:32:01

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[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 (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-12-14T12:23:11', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'e678f649-210f-432c-b503-11df74f73657'	System	14 Dec 2020 18:23:32
User entered 'No (N)'	System	14 Dec 2020 18:23:32

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Have you been exposed to someone with 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 (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-12-14T12:23:18', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'e678f649-210f-432c-b503-11df74f73657'	System	14 Dec 2020 18:23:32
User entered 'No (N)'	System	14 Dec 2020 18:23:32

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-12-14T12:23:26', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'e678f649-210f-432c-b503-11df74f73657'	System	14 Dec 2020 18:23:32
User entered '14 Dec 2020 12:23:26'	System	14 Dec 2020 18:23:32

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[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 (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-12-19T12:49:51', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '5d29ee4a-c47e-4783-92ad-0f939af0699f' User entered 'No (N)'	System	19 Dec 2020 18:50:12
	System	19 Dec 2020 18:50:12

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

Have you been exposed to someone with 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 (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-12-19T12:50:06', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '5d29ee4a-c47e-4783-92ad-0f939af0699f' User entered 'No (N)'	System	19 Dec 2020 18:50:12

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-12-19T12:50:09', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '5d29ee4a-c47e-4783-92ad-0f939af0699f' User entered '19 Dec 2020 12:50:09'	System	19 Dec 2020 18:50:12

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[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 (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-12-26T01:21:19', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '078e0f91-f843-4b95-a441-96ead539cc87' User entered 'No (N)'	System	26 Dec 2020 07:21:34

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

Have you been exposed to someone with 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 (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-12-26T01:21:25', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '078e0f91-f843-4b95-a441-96ead539cc87' User entered 'No (N)'	System	26 Dec 2020 07:21:34

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2020-12-26T01:21:28', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '078e0f91-f843-4b95-a441-96ead539cc87' User entered '26 Dec 2020 01:21:28'	System	26 Dec 2020 07:21:34
	System	26 Dec 2020 07:21:34

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[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 (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2021-01-02T10:02:16', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '0db4ebb2-1d67-4e4e-ab98-2b3b5b5d0356'	System	02 Jan 2021 16:03:32
User entered 'Yes (Y)'	System	02 Jan 2021 16:03:32

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Have you been exposed to someone with 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 (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2021-01-02T10:02:32', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '0db4ebb2-1d67-4e4e-ab98-2b3b5b5d0356'	System	02 Jan 2021 16:03:32
User entered 'No (N)'	System	02 Jan 2021 16:03:32

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2021-01-02T10:02:39', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '0db4ebb2-1d67-4e4e-ab98-2b3b5b5d0356'	System	02 Jan 2021 16:03:32
User entered 'No (N)'	System	02 Jan 2021 16:03:32

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2021-01-02T10:02:50', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '0db4ebb2-1d67-4e4e-ab98-2b3b5b5d0356'	System	02 Jan 2021 16:03:32
User entered 'Yes (Y)'	System	02 Jan 2021 16:03:32

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Please 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 (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2021-01-02T10:03:15', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '0db4ebb2-1d67-4e4e-ab98-2b3b5b5d0356'	System	02 Jan 2021 16:03:32
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	02 Jan 2021 16:03:32

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2021-01-02T10:03:22', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '0db4ebb2-1d67-4e4e-ab98-2b3b5b5d0356' User entered '02 Jan 2021 10:03:22'	System	02 Jan 2021 16:03:32

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[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 (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2021-01-11T12:39:43', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '6984a240-97b8-4ff6-9e85-064b9a6987b3' User entered 'No (N)'	System	11 Jan 2021 18:40:10
	System	11 Jan 2021 18:40:10

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

Have you been exposed to someone with 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 (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2021-01-11T12:39:50', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '6984a240-97b8-4ff6-9e85-064b9a6987b3' User entered 'No (N)'	System	11 Jan 2021 18:40:10

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2021-01-11T12:39:59', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '6984a240-97b8-4ff6-9e85-064b9a6987b3' User entered '11 Jan 2021 12:39:59'	System	11 Jan 2021 18:40:10
	System	11 Jan 2021 18:40:10

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[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 (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2021-01-16T07:59:09', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'f9e90663-8eae-4992-84ec-1c2668ea8aae'	System	16 Jan 2021 13:59:22
User entered 'No (N)'	System	16 Jan 2021 13:59:22

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Have you been exposed to someone with 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 (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2021-01-16T07:59:15', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'f9e90663-8eae-4992-84ec-1c2668ea8aae'	System	16 Jan 2021 13:59:22
User entered 'No (N)'	System	16 Jan 2021 13:59:22

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2021-01-16T07:59:19', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'f9e90663-8eae-4992-84ec-1c2668ea8aae' User entered '16 Jan 2021 07:59:19'	System	16 Jan 2021 13:59:22

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[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 (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2021-01-23T12:09:24', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '6b813e9d-d66b-4318-a066-39941973a4be' User entered 'No (N)'	System	23 Jan 2021 18:09:39

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Have you been exposed to someone with 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 (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2021-01-23T12:09:28', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '6b813e9d-d66b-4318-a066-39941973a4be'	System	23 Jan 2021 18:09:39
User entered 'No (N)'	System	23 Jan 2021 18:09:39

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2021-01-23T12:09:36', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '6b813e9d-d66b-4318-a066-39941973a4be' User entered '23 Jan 2021 12:09:36'	System	23 Jan 2021 18:09:39

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[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 (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2021-01-31T12:48:29', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '1f0d3b8f-7273-4b55-b000-05ee9f16437f' User entered 'No (N)'	System	31 Jan 2021 18:48:40

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Have you been exposed to someone with 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 (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2021-01-31T12:48:33', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '1f0d3b8f-7273-4b55-b000-05ee9f16437f' User entered 'No (N)'	System	31 Jan 2021 18:48:40

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2021-01-31T12:48:38', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '1f0d3b8f-7273-4b55-b000-05ee9f16437f' User entered '31 Jan 2021 12:48:38'	System	31 Jan 2021 18:48:40
	System	31 Jan 2021 18:48:40

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[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 (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2021-02-06T07:35:56', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'fc94800a-52a1-4258-8410-a03df643ec99'	System	06 Feb 2021 13:36:06
User entered 'No (N)'	System	06 Feb 2021 13:36:06

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

Have you been exposed to someone with 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 (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2021-02-06T07:35:59', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'fc94800a-52a1-4258-8410-a03df643ec99'	System	06 Feb 2021 13:36:06
User entered 'No (N)'	System	06 Feb 2021 13:36:06

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2021-02-06T07:36:03', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'fc94800a-52a1-4258-8410-a03df643ec99'	System	06 Feb 2021 13:36:06
User entered '06 Feb 2021 07:36:03'	System	06 Feb 2021 13:36:06

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[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 (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2021-02-13T18:30:49', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'd4c8da61-2ae0-4fd2-a0d8-c9aae759de96' User entered 'No (N)'	System	14 Feb 2021 00:31:30
	System	14 Feb 2021 00:31:30

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

Have you been exposed to someone with 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 (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2021-02-13T18:31:21', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'd4c8da61-2ae0-4fd2-a0d8-c9aae759de96'	System	14 Feb 2021 00:31:30
User entered 'No (N)'	System	14 Feb 2021 00:31:30

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2021-02-13T18:31:25', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'd4c8da61-2ae0-4fd2-a0d8-c9aae759de96'	System	14 Feb 2021 00:31:30
User entered '13 Feb 2021 18:31:25'	System	14 Feb 2021 00:31:30

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[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 (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2021-02-20T11:57:19', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'a3d6cafc-8873-45f7-adcd-f701b7ff0b95'	System	20 Feb 2021 17:57:49
User entered 'No (N)'	System	20 Feb 2021 17:57:49

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

Have you been exposed to someone with 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 (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2021-02-20T11:57:23', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'a3d6cafc-8873-45f7-adcd-f701b7ff0b95'	System	20 Feb 2021 17:57:49
User entered 'No (N)'	System	20 Feb 2021 17:57:49

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2021-02-20T11:57:45', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'a3d6cafc-8873-45f7-adcd-f701b7ff0b95' User entered '20 Feb 2021 11:57:45'	System	20 Feb 2021 17:57:49

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[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 (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2021-02-27T11:09:06-06:00', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '57c38b19-f734-4aa0-978a-530f9caad892'	System	27 Feb 2021 17:13:57
User entered 'No (N)'	System	27 Feb 2021 17:13:57

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

Have you been exposed to someone with 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 (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2021-02-27T11:09:16-06:00', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '57c38b19-f734-4aa0-978a-530f9caad892'	System	27 Feb 2021 17:13:57
User entered 'No (N)'	System	27 Feb 2021 17:13:57

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2021-02-27T11:09:23-06:00', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '57c38b19-f734-4aa0-978a-530f9caad892'	System	27 Feb 2021 17:13:57
User entered '27 Feb 2021 17:09:23'	System	27 Feb 2021 17:13:57

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[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 (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2021-03-06T11:46:24-06:00', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '5e194652-ebd9-4d08-b253-a3c2ddda1674'	System	06 Mar 2021 17:46:41
User entered 'No (N)'	System	06 Mar 2021 17:46:41

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

Have you been exposed to someone with 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 (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2021-03-06T11:46:29-06:00', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '5e194652-ebd9-4d08-b253-a3c2ddda1674'	System	06 Mar 2021 17:46:41
User entered 'No (N)'	System	06 Mar 2021 17:46:41

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2021-03-06T11:46:38-06:00', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '5e194652-ebd9-4d08-b253-a3c2ddda1674'	System	06 Mar 2021 17:46:41
User entered '06 Mar 2021 11:46:38'	System	06 Mar 2021 17:46:41

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[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 (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2021-03-14T19:37:28-05:00', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'a110bb72-7c44-48bc-b9e3-c13235fd3216'	System	15 Mar 2021 00:37:39
User entered 'No (N)'	System	15 Mar 2021 00:37:39

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

Have you been exposed to someone with 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 (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2021-03-14T19:37:32-05:00', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'a110bb72-7c44-48bc-b9e3-c13235fd3216'	System	15 Mar 2021 00:37:39
User entered 'No (N)'	System	15 Mar 2021 00:37:39

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2021-03-14T19:37:36-05:00', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'a110bb72-7c44-48bc-b9e3-c13235fd3216' User entered '14 Mar 2021 19:37:36'	System	15 Mar 2021 00:37:39
	System	15 Mar 2021 00:37:39

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[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 (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2021-03-20T11:09:45-05:00', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '9939a4a2-b73f-49cb-9d2a-8846df8b90a3'	System	20 Mar 2021 16:14:46
User entered 'No (N)'	System	20 Mar 2021 16:14:46

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

Have you been exposed to someone with 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 (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2021-03-20T11:09:48-05:00', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '9939a4a2-b73f-49cb-9d2a-8846df8b90a3'	System	20 Mar 2021 16:14:46
User entered 'No (N)'	System	20 Mar 2021 16:14:46

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2021-03-20T11:09:53-05:00', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '9939a4a2-b73f-49cb-9d2a-8846df8b90a3'	System	20 Mar 2021 16:14:46
User entered '20 Mar 2021 11:09:53'	System	20 Mar 2021 16:14:46

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[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 (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2021-03-27T07:55:21-05:00', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'b84c1bae-fe6-4f82-8a4d-c232f261d85a'	System	27 Mar 2021 12:55:37
User entered 'No (N)'	System	27 Mar 2021 12:55:37

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

Have you been exposed to someone with 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 (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2021-03-27T07:55:28-05:00', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'b84c1bae-fe6-4f82-8a4d-c232f261d85a'	System	27 Mar 2021 12:55:37
User entered 'No (N)'	System	27 Mar 2021 12:55:37

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2021-03-27T07:55:32-05:00', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'b84c1bae-fe6-4f82-8a4d-c232f261d85a' User entered '27 Mar 2021 07:55:32'	System	27 Mar 2021 12:55:37
	System	27 Mar 2021 12:55:37

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[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 (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2021-04-03T09:52:46-05:00', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '98b0cd51-9db8-40d0-a37a-53c8f91e92d6' User entered 'No (N)'	System	03 Apr 2021 14:53:03
	System	03 Apr 2021 14:53:03

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

Have you been exposed to someone with 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 (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2021-04-03T09:52:49-05:00', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '98b0cd51-9db8-40d0-a37a-53c8f91e92d6'	System	03 Apr 2021 14:53:03
User entered 'No (N)'	System	03 Apr 2021 14:53:03

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2021-04-03T09:52:58-05:00', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '98b0cd51-9db8-40d0-a37a-53c8f91e92d6'	System	03 Apr 2021 14:53:03
User entered '03 Apr 2021 09:52:58'	System	03 Apr 2021 14:53:03

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[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 (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2021-04-10T17:24:38-05:00', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'c48e70d6-5c92-4a2d-ace5-ce3d35e56575'	System	10 Apr 2021 22:25:43
User entered 'Yes (Y)'	System	10 Apr 2021 22:25:43

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

Have you been exposed to someone with 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 (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2021-04-10T17:24:27-05:00', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'c48e70d6-5c92-4a2d-ace5-ce3d35e56575'	System	10 Apr 2021 22:25:43
User entered 'No (N)'	System	10 Apr 2021 22:25:43

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2021-04-10T17:24:45-05:00', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'c48e70d6-5c92-4a2d-ace5-ce3d35e56575'	System	10 Apr 2021 22:25:43
User entered 'No (N)'	System	10 Apr 2021 22:25:43

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2021-04-10T17:25:04-05:00', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'c48e70d6-5c92-4a2d-ace5-ce3d35e56575'	System	10 Apr 2021 22:25:43
User entered 'Yes (Y)'	System	10 Apr 2021 22:25:43

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

Please 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 (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2021-04-10T17:25:22-05:00', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'c48e70d6-5c92-4a2d-ace5-ce3d35e56575'	System	10 Apr 2021 22:25:43
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	10 Apr 2021 22:25:43

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2021-04-10T17:25:34-05:00', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'c48e70d6-5c92-4a2d-ace5-ce3d35e56575'	System	10 Apr 2021 22:25:43
User entered '10 Apr 2021 17:25:34'	System	10 Apr 2021 22:25:43

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[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 (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2021-04-17T08:14:54-05:00', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '69675d23-26c7-4fbc-8935-f79cf78be8f4'	System	17 Apr 2021 13:15:16
User entered 'No (N)'	System	17 Apr 2021 13:15:16

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Have you been exposed to someone with 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 (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2021-04-17T08:14:58-05:00', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '69675d23-26c7-4fbc-8935-f79cf78be8f4'	System	17 Apr 2021 13:15:16
User entered 'No (N)'	System	17 Apr 2021 13:15:16

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2021-04-17T08:15:14-05:00', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '69675d23-26c7-4fbc-8935-f79cf78be8f4'	System	17 Apr 2021 13:15:16
User entered '17 Apr 2021 08:15:14'	System	17 Apr 2021 13:15:16

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[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 (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2021-04-24T06:54:17-05:00', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'b0d99f55-bd97-4b6a-9372-3190f3226a9c'	System	24 Apr 2021 11:54:31
User entered 'No (N)'	System	24 Apr 2021 11:54:31

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

Have you been exposed to someone with 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 (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2021-04-24T06:54:23-05:00', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'b0d99f55-bd97-4b6a-9372-3190f3226a9c'	System	24 Apr 2021 11:54:31
User entered 'No (N)'	System	24 Apr 2021 11:54:31

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2021-04-24T06:54:27-05:00', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: 'b0d99f55-bd97-4b6a-9372-3190f3226a9c'	System	24 Apr 2021 11:54:31
User entered '24 Apr 2021 06:54:27'	System	24 Apr 2021 11:54:31

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[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 (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2021-05-01T11:34:34-05:00', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '7a57f2d6-c273-44ef-b7d9-7a232cb8d472'	System	01 May 2021 16:35:00
User entered 'No (N)'	System	01 May 2021 16:35:00

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

Have you been exposed to someone with 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 (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2021-05-01T11:34:46-05:00', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '7a57f2d6-c273-44ef-b7d9-7a232cb8d472'	System	01 May 2021 16:35:00
User entered 'No (N)'	System	01 May 2021 16:35:00

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2021-05-01T11:34:57-05:00', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '7a57f2d6-c273-44ef-b7d9-7a232cb8d472'	System	01 May 2021 16:35:00
User entered '01 May 2021 11:34:57'	System	01 May 2021 16:35:00

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 00:02:38

US3312197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:02:38
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 00:02:38

US3312197

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:01:02

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 12:16:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2021-02-27T11:10:58-06:00', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '57071a3f-5028-42f6-9313-851578c2533f' User entered 'No (N)'	System	27 Feb 2021 17:15:05
	System	27 Feb 2021 17:15:05

US3312197

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:01:02

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 12:16:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EFB5BAED-DFC7-4982-9696-FBB3A2661910)', Time: '2021-02-27T11:11:30-06:00', User OID: 'PatientReportedOutcome (US3312197)', ODM File OID: '57071a3f-5028-42f6-9313-851578c2533f' User entered '27 Feb 2021 17:11:30'	System	27 Feb 2021 17:15:05
	System	27 Feb 2021 17:15:05

US3312197

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 16:48:14

US3312197

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:02

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered '12 Nov 2020'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 16:48:14

US3312197

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 16:48:14

US3312197

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 16:48:14

US3312197

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered 'Yes (Y)'	(b) (4) Monica Atwood (b) (4)	28 Dec 2020 17:14:58

US3312197

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:06:45
User entered 'I'	System	28 Dec 2020 17:14:58

US3312197

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:45:14
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:25:04

US3312197

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:02

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:45:14
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered '17 Dec 2020'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:25:04

US3312197

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:45:14
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:25:04

US3312197

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:45:14
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:25:04

US3312197

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:45:14
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:25:07

US3312197

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:45:14
User entered 'I'	System	28 Dec 2020 17:25:07

US3312197

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:45:14
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:49:47

US3312197

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:02

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:45:14
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered '13 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:49:47

US3312197

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:45:14
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:49:47

US3312197

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:45:14
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:49:47

US3312197

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:45:14
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:49:51

US3312197

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:45:14
User entered 'I'	System	22 Jan 2021 19:49:51

US3312197

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:45:14
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Feb 2021 22:40:32

US3312197

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:45:14
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered '11 Feb 2021'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Feb 2021 22:40:32

US3312197

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:45:14
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karol Moore (b) (4) (b) (4)	26 Feb 2021 22:40:32

US3312197

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:45:14
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered empty.	(b) (4)	26 Feb 2021 22:40:32
	Karol Moore (b) (4)	
	(b) (4)	

US3312197

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:45:14
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	26 Feb 2021 22:40:36

US3312197

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:45:14
User entered 'I'	System	26 Feb 2021 22:40:36

US3312197

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:01:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:45:14
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 20:36:29

US3312197

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:45:14
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered '02 Mar 2021'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 20:36:29

US3312197

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:01:02

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:45:14
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 20:36:29

US3312197

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:01:02

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:45:14
User entered 'VISIT4'	System	03 Mar 2021 20:36:29

US3312197

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:45:14
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:04:42

US3312197

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:45:14
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:04:42

US3312197

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:45:14
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:04:42

US3312197

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:45:14
User entered empty.	System	29 Mar 2021 20:04:42

US3312197

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:45:14
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:04:42

US3312197

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:45:14
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:04:42

US3312197

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:45:14
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:04:42

US3312197

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:45:14
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:04:42

US3312197

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:45:14
User entered empty.	System	29 Mar 2021 20:04:42

US3312197

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:45:14
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:04:42

US3312197

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:45:14
User entered empty.	System	29 Mar 2021 20:04:42

US3312197

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:45:14
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:04:42

US3312197

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:45:14
User entered empty.	System	29 Mar 2021 20:04:42

US3312197

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:45:14
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:04:42

US3312197

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:45:14
User entered empty.	System	29 Mar 2021 20:04:42

US3312197

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:45:14

US3312197

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:45:14

US3312197

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:01:02

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:45:14
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	03 Mar 2021 20:37:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Mar 2021 20:36:36

US3312197

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:01:02

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:45:14
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	03 Mar 2021 20:37:07
User entered '02 Mar 2021'	(b) (4), (b) (6)	03 Mar 2021 20:36:36

US3312197

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:01:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:45:14
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 20:36:51

US3312197

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:01:02

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:45:14
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered '02 Mar 2021'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 20:36:51

US3312197

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:01:02

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:45:14
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered '13:42'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 20:36:51

US3312197

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:01:02

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:45:14
User entered '02 Mar 2021 13:42'	System	03 Mar 2021 20:36:51

US3312197

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:45:14
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 20:37:17

US3312197

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:45:14
User entered 'I'	System	03 Mar 2021 20:37:17

US3312197

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
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).	(b) (4) System	16 Apr 2021 18:38:16
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	16 Apr 2021 12:53:46
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4)	16 Apr 2021 12:53:46

US3312197

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User entered '13 Apr 2021'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:53:46

US3312197

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Karol Moore (b) (4)	16 Apr 2021 18:38:16
reason for change: Data Entry Error	(b) (4)	
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 12:53:46

US3312197

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:53:46

US3312197

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:08:54

US3312197

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:02

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Apr 2021 13:08:54

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:01:02

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:41
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '24 Nov 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:30:00

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:01:02

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:41
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '11:22'	(b) (4)	25 Nov 2020 21:30:00
	Karol Moore (b) (4)	
	(b) (4)	

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:01:02

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:41
User entered '24 Nov 2020 11:22'	System	25 Nov 2020 21:30:00

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:01:02

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:41
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Safety Call (Safety Call)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:30:00

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:01:02

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:41
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:30:00

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:01:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Day 1 (Day 1)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:31:05

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:01:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '22 Nov 2020'	(b) (4) Karol Moore (b) (4)	25 Nov 2020 21:31:05
	(b) (4)	

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:01:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:31:05

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:01:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Dec 2020 18:07:47
User entered empty.	Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:31:05

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:01:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User entered '%'	System	18 Dec 2020 18:07:47
User entered empty.	System	25 Nov 2020 21:31:05

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:01:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Dec 2020 18:07:47
User entered empty.	Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:31:05

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:01:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:31:05

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:01:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Moderate (Moderate)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:31:05

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:01:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Moderate (Moderate)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:31:05

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:01:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Moderate (Moderate)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:31:05

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:01:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Moderate (Moderate)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:31:05

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:01:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:31:05

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:01:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:31:05

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:01:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Moderate (Moderate)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:31:05

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:01:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:31:05

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:01:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:31:05

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:01:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Moderate (Moderate)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:31:05

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:01:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Moderate (Moderate)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:31:05

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:01:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:31:05

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:01:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:31:05

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:01:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Moderate (Moderate)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:31:05

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:01:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Moderate (Moderate)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:31:05

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:01:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Day 2 (Day 2)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:32:41

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:01:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '23 Nov 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:32:41

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:01:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:32:41

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:01:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Dec 2020 18:07:47
User entered empty.	Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:32:41

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:01:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User entered '%'	System	18 Dec 2020 18:07:47
User entered empty.	System	25 Nov 2020 21:32:41

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:01:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Dec 2020 18:07:47
User entered empty.	Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:32:41

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:01:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:32:41

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:01:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Moderate (Moderate)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:32:41

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:01:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Moderate (Moderate)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:32:41

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:01:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Moderate (Moderate)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:32:41

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:01:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Moderate (Moderate)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:32:41

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:01:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	25 Nov 2020 21:32:41
	(b) (4)	

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:01:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:32:41

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:01:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Moderate (Moderate)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:32:41

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:01:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:32:41

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:01:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:32:41

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:01:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Moderate (Moderate)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:32:41

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:01:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Moderate (Moderate)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:32:41

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:01:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:32:41

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:01:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:32:41

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:01:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:32:41

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:01:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:32:41

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:01:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Day 3 (Day 3)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:33:09

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:01:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '24 Nov 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:33:09

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:01:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:33:09

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:01:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '95' reason for change: Data Entry Error	(b) (4)	25 Nov 2020 22:16:39
User entered empty.	Karol Moore (b) (4)	25 Nov 2020 21:33:09
	(b) (4)	

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:01:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User entered '%'	System	25 Nov 2020 22:16:39
User entered empty.	System	25 Nov 2020 21:33:09

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:01:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '97.7' F reason for change: Data Entry Error	(b) (4)	25 Nov 2020 22:16:39
User entered empty.	Karol Moore (b) (4)	25 Nov 2020 21:33:09
	(b) (4)	

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:01:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:33:09

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:01:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Moderate (Moderate)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:33:09

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:01:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Moderate (Moderate)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:33:09

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:01:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Moderate (Moderate)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:33:09

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:01:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Moderate (Moderate)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:33:09

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:01:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	25 Nov 2020 21:33:09
	(b) (4)	

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:01:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:33:09

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:01:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Moderate (Moderate)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:33:09

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:01:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:33:09

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:01:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:33:09

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:01:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Moderate (Moderate)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:33:09

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:01:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Moderate (Moderate)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:33:09

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:01:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:33:09

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:01:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:33:09

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:01:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:33:09

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:01:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:33:09

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:01:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Day 4 (Day 4)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:59:14

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:01:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '25 Nov 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:59:14

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:01:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:59:14

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:01:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '91'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:59:14

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:01:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User entered '%'	System	01 Dec 2020 14:59:14

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:01:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '98.8' F	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:59:14

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:01:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:59:14

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:01:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Moderate (Moderate)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:59:14

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:01:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Moderate (Moderate)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:59:14

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:01:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Moderate (Moderate)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:59:14

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:01:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Moderate (Moderate)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:59:14

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:01:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Moderate (Moderate)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:59:14

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:01:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:59:14

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:01:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Moderate (Moderate)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:59:14

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:01:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:59:14

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:01:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:59:14

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:01:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:59:14

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:01:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:59:14

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:01:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:59:14

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:01:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:59:14

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:01:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Moderate (Moderate)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:59:14

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:01:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:59:14

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:01:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Day 5 (Day 5)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:59:58

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:01:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '26 Nov 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:59:58

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:01:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:59:58

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:01:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '92'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:59:58

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:01:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User entered '%'	System	01 Dec 2020 14:59:58

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:01:02

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '98.7' F	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:59:58

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:01:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:59:58

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:01:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Moderate (Moderate)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:59:58

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:01:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:59:58

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:01:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:59:58

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:01:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Moderate (Moderate)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:59:58

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:01:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:59:58

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:01:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:59:58

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:01:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:59:58

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:01:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:59:58

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:01:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:59:58

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:01:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:59:58

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:01:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:59:58

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:01:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:59:58

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:01:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:59:58

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:01:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Moderate (Moderate)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:59:58

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:01:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:59:58

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:01:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Day 6 (Day 6)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:02:45

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:01:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '27 Nov 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:02:45

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:01:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:02:45

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:01:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '93'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:02:45

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:01:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User entered '%'	System	01 Dec 2020 15:02:45

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:01:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '97.8' F	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:02:45

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:01:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'None (None)'	(b) (4)	01 Dec 2020 15:02:45
	Karol Moore (b) (4)	
	(b) (4)	

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:01:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:02:45

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:01:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:02:45

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:01:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:02:45

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:01:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Moderate (Moderate)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:02:45

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:01:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	01 Dec 2020 15:02:45
	(b) (4)	

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:01:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:02:45

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:01:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:02:45

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:01:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:02:45

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:01:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:02:45

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:01:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:02:45

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:01:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	01 Dec 2020 15:02:45
	(b) (4)	

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:01:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:02:45

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:01:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:02:45

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:01:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:02:45

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:01:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:02:45

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:01:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Day 7 (Day 7)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:03:47

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:01:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '28 Nov 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:03:47

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:01:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:03:47

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:01:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '74'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:03:47

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:01:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User entered '%'	System	01 Dec 2020 15:03:47

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:01:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '97.7' F	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:03:47

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:01:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	01 Dec 2020 15:03:47

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:01:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Moderate (Moderate)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:03:47

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:01:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Severe (Severe)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:03:47

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:01:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Severe (Severe)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:03:47

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:01:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Moderate (Moderate)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:03:47

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:01:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	01 Dec 2020 15:03:47
	(b) (4)	

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:01:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:03:47

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:01:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Severe (Severe)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:03:47

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:01:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	01 Dec 2020 15:03:47
	(b) (4)	

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:01:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	01 Dec 2020 15:03:47

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:01:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:03:47

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:01:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:03:47

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:01:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:03:47

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:01:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:03:47

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:01:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Moderate (Moderate)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:03:47

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:01:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:03:47

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:01:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Day 8 (Day 8)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:04:35

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:01:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '29 Nov 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:04:35

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:01:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:04:35

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:01:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '93'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:04:35

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:01:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User entered '%'	System	01 Dec 2020 15:04:35

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:01:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '97.7' F	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:04:35

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:01:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	01 Dec 2020 15:04:35

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:01:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Moderate (Moderate)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:04:35

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:01:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Moderate (Moderate)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:04:35

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:01:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Moderate (Moderate)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:04:35

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:01:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Moderate (Moderate)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:04:35

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:01:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:04:35

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:01:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:04:35

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:01:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Severe (Severe)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:04:35

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:01:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:04:35

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:01:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:04:35

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:01:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:04:35

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:01:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Mild (Mild)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:04:35

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:01:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'None (None)'	(b) (4) Karol Moore (b) (4)	01 Dec 2020 15:04:35

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:01:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:04:35

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:01:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Moderate (Moderate)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:04:35

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:01:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'None (None)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:04:35

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:01:02

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:54
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:11:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '24 Nov 2020'	(b) (4)	
	Karol Moore (b) (4)	01 Dec 2020 14:53:10
	(b) (4)	

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:01:02

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:54
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:11:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Yes (Y)'	Karol Moore (b) (4)	01 Dec 2020 14:53:10

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:01:02

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:54
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:11:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4) (b) (4), (b) (6)	09 Dec 2020 05:20:33
User entered 'No (N)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:54:57
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'confirmed' (Site from System).	Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:53:25
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	01 Dec 2020 14:53:10
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:53:10

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:01:02

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:54
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:11:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '24 Nov 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:53:10

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:01:02

Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:54
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:11:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Karol Moore (b) (4)	01 Dec 2020 14:53:10

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:01:02

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:54
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:11:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered empty.	(b) (4)	01 Dec 2020 14:53:10
	Karol Moore (b) (4)	
	(b) (4)	

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:01:02

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:54
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:11:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'No (N)'	(b) (4)	01 Dec 2020 14:53:10
	Karol Moore (b) (4)	
	(b) (4)	

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:01:02

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:54
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:11:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered empty.	(b) (4)	01 Dec 2020 14:53:10
	Karol Moore (b) (4)	
	(b) (4)	

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:01:02

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:54
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:11:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered empty.	(b) (4)	01 Dec 2020 14:53:10
	Karol Moore (b) (4)	
	(b) (4)	

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:01:02

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:54
User entered '0'	System	01 Dec 2020 14:54:57
User entered '1'	System	01 Dec 2020 14:53:10

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:01:02

Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:59
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:18:45
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:54:04

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:01:02

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:59
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:18:45
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:54:04

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:01:02

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:59
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:18:45
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:54:04

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:01:02

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:59
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:18:45
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:54:04

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:01:02

[Did the subject have Heart Rate \$\geq\$ 125 beats per minute](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:59
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:18:45
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:54:04

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:59
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:18:45
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:54:04

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:59
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:18:45
User entered empty.	(b) (4)	01 Dec 2020 14:54:04
	Karol Moore (b) (4)	
	(b) (4)	

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:01:02

[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:59
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:18:45
User entered empty.	(b) (4)	01 Dec 2020 14:54:04
	Karol Moore (b) (4)	
	(b) (4)	

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:01:02

Did the subject have Oxygen Saturation of SpO2 \leq 93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:59
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:18:45
User closed query 'Per CDM: Synptom Log as Days 4-8 recorded with O2 Saturations of 91, 92, 93, 74, and 93 percents yet 'Did the subject have Oxygen Saturation of SpO2 \leq 93% on room air at sea level?' is recorded as No. Please review and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Apr 2021 06:24:10
Query 'Per CDM: Synptom Log as Days 4-8 recorded with O2 Saturations of 91, 92, 93, 74, and 93 percents yet 'Did the subject have Oxygen Saturation of SpO2 \leq 93% on room air at sea level?' is recorded as No. Please review and update accordingly.'	(b) (4), (b) (6)	07 Apr 2021 21:30:49
answered with 'Please advise: o2 sats vary across dates, only 1field to enter 1 value. Also: This is non Covid pneumonia.' (Site from DM).		
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 21:29:48
User opened query 'Per CDM: Synptom Log as Days 4-8 recorded with O2 Saturations of 91, 92, 93, 74, and 93 percents yet 'Did the subject have Oxygen Saturation of SpO2 \leq 93% on room air at sea level?' is recorded as No. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 15:40:25
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:54:04

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:01:02

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:59
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:18:45
User entered '25 Nov 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:29:48
User entered empty.	Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:54:04

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:01:02

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:59
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:18:45
User entered '29 Nov 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:29:48
User entered empty.	Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:54:04

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:01:02

[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:59
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:18:45
User entered '93' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:29:48
User entered empty.	Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:54:04

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:01:02

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:59
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:18:45
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:54:04

US3312197

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:59
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:18:45
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:54:04

US3312197

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:59
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:18:45
User entered empty.	(b) (4)	01 Dec 2020 14:54:04
	Karol Moore (b) (4)	
	(b) (4)	

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:01:02

[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:59
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:18:45
User entered empty.	(b) (4) Karol Moore (b) (4)	01 Dec 2020 14:54:04

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:01:02

[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:59
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:18:45
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:54:04

US3312197

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Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:01:02

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:59
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:18:45
User entered empty.	(b) (4)	01 Dec 2020 14:54:04
	Karol Moore (b) (4)	
	(b) (4)	

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:01:02

[Did the subject have Acute Respiratory Distress Syndrome \(ARDS\)?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:59
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:18:45
User entered 'No (N)'	(b) (4)	01 Dec 2020 14:54:04
	Karol Moore (b) (4)	
	(b) (4)	

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:59
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:18:45
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:54:04

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:01:02

[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:59
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:18:45
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:54:04

US3312197

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:59
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:18:45
User entered empty.	(b) (4)	01 Dec 2020 14:54:04
	Karol Moore (b) (4)	
	(b) (4)	

US3312197

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:59
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:18:45
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:54:04

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:01:02

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:59
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:18:45
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:54:04

US3312197

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:59
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:18:45
User entered empty.	(b) (4)	01 Dec 2020 14:54:04
	Karol Moore (b) (4)	
	(b) (4)	

US3312197

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:59
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:18:45
User entered empty.	(b) (4)	01 Dec 2020 14:54:04
	Karol Moore (b) (4)	
	(b) (4)	

US3312197

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Generated On: 09 Jun 2021 17:01:02

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:59
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:18:45
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:54:04

US3312197

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:59
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:18:45
User entered empty.	(b) (4)	01 Dec 2020 14:54:04
	Karol Moore (b) (4)	
	(b) (4)	

US3312197

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:59
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:18:45
User entered empty.	(b) (4)	01 Dec 2020 14:54:04
	Karol Moore (b) (4)	
	(b) (4)	

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:01:02

[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:59
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:18:45
User entered empty.	(b) (4)	01 Dec 2020 14:54:04
	Karol Moore (b) (4)	
	(b) (4)	

US3312197

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:59
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:18:45
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:54:04

US3312197

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:59
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:18:45
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:54:04

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:01:02

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:59
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:18:45
User closed query 'Per DM: it appears that 'Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg' is recorded as NO yet there is a record for Diastolic Blood Pressure as 58mmHg in Illness Visit dated 24NOV2020. Please review and reconcile.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Apr 2021 06:24:17
Query 'Per DM: it appears that 'Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg' is recorded as NO yet there is a record for Diastolic Blood Pressure as 58mmHg in Illness Visit dated 24NOV2020. Please review and reconcile.'	(b) (4), (b) (6)	07 Apr 2021 21:31:22
answered with 'updated' (Site from DM).		
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 21:31:16
User opened query 'Per DM: it appears that 'Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg' is recorded as NO yet there is a record for Diastolic Blood Pressure as 58mmHg in Illness Visit dated 24NOV2020. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 21:04:45
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:54:04

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:59
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:18:45
User entered '24 Nov 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:31:16
User entered empty.	Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:54:04

US3312197

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:59
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:18:45
User entered '24 Nov 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:31:16
User entered empty.	Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:54:04

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:01:02

[Evidence of Shock Requires
Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:59
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:18:45
User entered 'No (N)'	Karol Moore (b) (4)	01 Dec 2020 14:54:04

US3312197

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:59
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:18:45
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:54:04

US3312197

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Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:59
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:18:45
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:54:04

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

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[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:59
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:18:45
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:54:04

US3312197

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Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:59
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:18:45
User entered empty.	(b) (4)	01 Dec 2020 14:54:04
	Karol Moore (b) (4)	
	(b) (4)	

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

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Generated On: 09 Jun 2021 17:01:02

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:59
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:18:45
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:54:04

US3312197

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User entered empty.	(b) (4)	01 Dec 2020 14:54:04
	Karol Moore (b) (4)	
	(b) (4)	

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:01:02

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:59
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:18:45
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:54:04

US3312197

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User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:54:04

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:01:02

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:59
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:18:45
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:54:04

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:01:02

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:59
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:18:45
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:54:04

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:01:02

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:59
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:18:45
User entered 'No (N)'	(b) (4)	01 Dec 2020 14:54:04
	Karol Moore (b) (4)	
	(b) (4)	

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:01:02

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:59
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:18:45
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:54:04

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:01:02

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:59
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:18:45
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:54:04

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:01:02

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:59
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:18:45
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:54:04

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:01:02

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:03:59
User signature succeeded.	Carlos Fierro (b) (4)	08 Apr 2021 15:18:45
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 14:54:04

US3312197

Folder: Covid-19 Assessment 24 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:01:02

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:04:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'No (N)'	(b) (4) Kelly Moen (b) (4) (b) (4)	10 Dec 2020 22:32:06

US3312197

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:01:02

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Karol Moore (b) (4) (b) (4)	02 Dec 2020 21:12:00

US3312197

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:01:02

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	02 Dec 2020 21:12:00
	(b) (4)	

US3312197

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:01:02

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
	(b) (4)	
User entered '26 Nov 2020'	Karol Moore (b) (4)	02 Dec 2020 21:12:00
	(b) (4)	

US3312197

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:01:02

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Karol Moore (b) (4) (b) (4)	02 Dec 2020 21:12:00

US3312197

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:01:02

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	02 Dec 2020 21:12:00
	(b) (4)	

US3312197

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:01:02

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
	(b) (4)	
User entered '28 Nov 2020'	Karol Moore (b) (4)	02 Dec 2020 21:12:00
	(b) (4)	

US3312197

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:01:02

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Karol Moore (b) (4) (b) (4)	02 Dec 2020 21:12:00

US3312197

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:01:02

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Karol Moore (b) (4)	02 Dec 2020 21:12:00
	(b) (4)	

US3312197

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:01:02

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	02 Dec 2020 21:12:00
	(b) (4)	

US3312197

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:01:02

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Karol Moore (b) (4) (b) (4)	02 Dec 2020 21:12:00

US3312197

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:01:02

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Karol Moore (b) (4)	02 Dec 2020 21:12:00
	(b) (4)	

US3312197

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:01:02

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	02 Dec 2020 21:12:00
	(b) (4)	

US3312197

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:01:02

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Karol Moore (b) (4) (b) (4)	02 Dec 2020 21:12:00

US3312197

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:01:02

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Karol Moore (b) (4)	02 Dec 2020 21:12:00
	(b) (4)	

US3312197

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:01:02

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	02 Dec 2020 21:12:00
	(b) (4)	

US3312197

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:01:02

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Karol Moore (b) (4) (b) (4)	02 Dec 2020 21:12:00

US3312197

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:01:02

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Karol Moore (b) (4)	02 Dec 2020 21:12:00
	(b) (4)	

US3312197

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:01:02

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	02 Dec 2020 21:12:00
	(b) (4)	

US3312197

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:01:02

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Karol Moore (b) (4) (b) (4)	02 Dec 2020 21:12:00

US3312197

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:01:02

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Karol Moore (b) (4)	02 Dec 2020 21:12:00
	(b) (4)	

US3312197

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:01:02

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	02 Dec 2020 21:12:00
	(b) (4)	

US3312197

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:01:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:05
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:33:36

US3312197

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:05
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '24 Nov 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:33:36

US3312197

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:01:02

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:05
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Clinic (Clinic)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:33:36

US3312197

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:01:02

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:05
User entered 'SICKD1'	System	25 Nov 2020 21:33:36

US3312197

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:05
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:34:32

US3312197

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:05
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '24 Nov 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:34:32

US3312197

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:05
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '14:03'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:34:32

US3312197

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:05
User entered '24 Nov 2020 14:03'	System	25 Nov 2020 21:34:32

US3312197

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:05
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '66' in	(b) (4)	25 Nov 2020 21:34:32
DataPoint set to visible.	Karol Moore (b) (4)	25 Nov 2020 21:33:36
	(b) (4)	
	System	

US3312197

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:05
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '247.4' lb	(b) (4) Karol Moore (b) (4)	25 Nov 2020 21:34:32
DataPoint set to visible.	(b) (4) System	25 Nov 2020 21:33:36

US3312197

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:05
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '97.7' F	(b) (4)	25 Nov 2020 21:34:32
	Karol Moore (b) (4)	
	(b) (4)	

US3312197

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:05
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:34:32

US3312197

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:05
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:34:32

US3312197

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:05
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '78'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:34:32

US3312197

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:05
User entered 'bpm'	System	25 Nov 2020 21:34:32

US3312197

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:05
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '22'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:34:32

US3312197

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:05
User entered 'breaths/min'	System	25 Nov 2020 21:34:32

US3312197

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:05
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '132'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:34:32

US3312197

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:05
User entered 'mmHg'	System	25 Nov 2020 21:34:32

US3312197

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:05
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	27 Nov 2020 12:06:41
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'CORRECT AS ENTERED. NCS. PER PROTOCOL TOXICITY TABLE DIASTOLIC BLOOD PRESSURE IS NOT DEFINED. Not AE' (Site from System).	Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:34:52
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		25 Nov 2020 21:34:32
User entered '58'	Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:34:32

US3312197

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:05
User entered 'mmHg'	System	25 Nov 2020 21:34:32

US3312197

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:05

US3312197

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:05

US3312197

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:01:02

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:05
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:35:03

US3312197

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:01:02

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:05
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '24 Nov 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:35:03

US3312197

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 17:01:02

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:05
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:35:13

US3312197

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 17:01:02

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:49:05
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 24 NOV 2020 is recorded under illness Visit Day 1 visit in EDC, however the same SARS-CoV-2 serum sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Dec 2020 11:45:38
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 24 NOV 2020 is recorded under illness Visit Day 1 visit in EDC, however the same SARS-CoV-2 serum sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with '1F6091R' (Site from DM).	Karol Moore (b) (4) (b) (4)	23 Dec 2020 14:56:46
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 24 NOV 2020 is recorded under illness Visit Day 1 visit in EDC, however the same SARS-CoV-2 serum sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 06:20:28
User entered '24 Nov 2020'	Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:35:13

US3312197

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:01:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	01 Dec 2020 15:04:55
	(b) (4)	

US3312197

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	01 Dec 2020 15:04:55
	(b) (4)	

US3312197

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:01:02

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	01 Dec 2020 15:04:55
	(b) (4)	

US3312197

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:01:02

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	01 Dec 2020 15:04:55

US3312197

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	01 Dec 2020 15:05:02
	(b) (4)	

US3312197

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	01 Dec 2020 15:05:02
	(b) (4)	

US3312197

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	01 Dec 2020 15:05:02
	(b) (4)	

US3312197

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Dec 2020 15:05:02

US3312197

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	01 Dec 2020 15:05:02
	(b) (4)	

US3312197

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	01 Dec 2020 15:05:02
	(b) (4)	

US3312197

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	01 Dec 2020 15:05:02
	(b) (4)	

US3312197

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	01 Dec 2020 15:05:02
	(b) (4)	

US3312197

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Dec 2020 15:05:02

US3312197

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	01 Dec 2020 15:05:02
	(b) (4)	

US3312197

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Dec 2020 15:05:02

US3312197

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	01 Dec 2020 15:05:02
	(b) (4)	

US3312197

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Dec 2020 15:05:02

US3312197

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	01 Dec 2020 15:05:02
	(b) (4)	

US3312197

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Dec 2020 15:05:02

US3312197

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:01:02

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	01 Dec 2020 15:05:10
	(b) (4)	

US3312197

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:01:02

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	01 Dec 2020 15:05:10
	(b) (4)	

US3312197

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 09 Jun 2021 17:01:02

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	01 Dec 2020 15:05:13
	(b) (4)	

US3312197

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 09 Jun 2021 17:01:02

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	01 Dec 2020 15:05:13
	(b) (4)	

US3312197

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

Form: Visit Date

Generated On: 09 Jun 2021 17:01:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 19:30:46

US3312197

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

Form: Visit Date

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
	(b) (4)	
User entered '12 Jan 2021'	(b) (4), (b) (6)	22 Jan 2021 19:30:46

US3312197

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

Form: Visit Date

Generated On: 09 Jun 2021 17:01:02

[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 13:11:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
	(b) (4)	
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	22 Jan 2021 19:30:46

US3312197

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

Form: Visit Date

Generated On: 09 Jun 2021 17:01:02

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User entered 'UNBLND_DECIDE'	System	22 Jan 2021 19:30:46

US3312197

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

Form: Unblinding

Generated On: 09 Jun 2021 17:01:02

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
	(b) (4)	
User entered '12 Jan 2021'	(b) (4), (b) (6)	22 Jan 2021 19:40:01

US3312197

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

Form: Unblinding

Generated On: 09 Jun 2021 17:01:02

[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 13:11:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
	(b) (4)	
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:20:21

US3312197

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

Form: Unblinding

Generated On: 09 Jun 2021 17:01:02

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 19:40:01

US3312197

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

Form: Unblinding

Generated On: 09 Jun 2021 17:01:02

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
	(b) (4)	
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:20:21

US3312197

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

Form: Unblinding

Generated On: 09 Jun 2021 17:01:02

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
	(b) (4)	
User entered '12 Jan 2021'	(b) (4), (b) (6)	22 Jan 2021 19:40:01

US3312197

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

Form: Unblinding

Generated On: 09 Jun 2021 17:01:02

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
	(b) (4)	
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	22 Jan 2021 19:40:01

US3312197

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

Form: Unblinding

Generated On: 09 Jun 2021 17:01:02

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
	(b) (4)	
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	22 Jan 2021 19:40:01

US3312197

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

Form: Unblinding

Generated On: 09 Jun 2021 17:01:02

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
	(b) (4)	
User entered 'Not Administered (NA)'	(b) (4), (b) (6)	22 Jan 2021 19:40:01

US3312197

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

Form: Unblinding

Generated On: 09 Jun 2021 17:01:02

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 19:40:01

US3312197

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

Form: Unblinding

Generated On: 09 Jun 2021 17:01:02

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User entered empty.	System	22 Jan 2021 19:40:01

US3312197

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

Form: Unblinding

Generated On: 09 Jun 2021 17:01:02

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User entered '1'	System	22 Jan 2021 19:40:01

US3312197

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:01:02

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
	(b) (4)	
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Jan 2021 19:42:29

US3312197

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:01:02

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
	(b) (4)	
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Jan 2021 19:42:29

US3312197

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:01:02

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User entered empty.	System	22 Jan 2021 19:42:29
DataPoint set to visible.	System	22 Jan 2021 19:40:01

US3312197

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:01:02

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
	(b) (4)	
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Jan 2021 19:42:29

US3312197

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:01:02

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
	(b) (4)	
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Jan 2021 19:42:29

US3312197

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:01:02

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User entered empty.	System	22 Jan 2021 19:42:29
DataPoint set to visible.	System	22 Jan 2021 19:40:01

US3312197

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:02

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	22 Jan 2021 19:42:29

US3312197

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 19:42:29

US3312197

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
	(b) (4)	
User entered '12 Jan 2021'	(b) (4), (b) (6)	22 Jan 2021 19:42:29

US3312197

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
	(b) (4)	
User entered '13:26'	(b) (4), (b) (6)	22 Jan 2021 19:42:29

US3312197

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:02

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User entered '12 Jan 2021 13:26'	System	22 Jan 2021 19:42:29

US3312197

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
	(b) (4)	
User entered '98.1' F	(b) (4), (b) (6)	22 Jan 2021 19:42:29

US3312197

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
	(b) (4)	
User entered 'Oral (Oral)'	(b) (4), (b) (6)	22 Jan 2021 19:42:29

US3312197

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 19:42:29

US3312197

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
	(b) (4)	
User entered '75'	(b) (4), (b) (6)	22 Jan 2021 19:42:29

US3312197

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User entered 'bpm'	System	22 Jan 2021 19:42:29

US3312197

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:02

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
	(b) (4)	
User entered '16'	(b) (4), (b) (6)	22 Jan 2021 19:42:29

US3312197

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User entered 'breaths/min'	System	22 Jan 2021 19:42:29

US3312197

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
	(b) (4)	
User entered '133'	(b) (4), (b) (6)	22 Jan 2021 19:42:29

US3312197

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User entered 'mmHg'	System	22 Jan 2021 19:42:29

US3312197

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
	(b) (4)	
User entered '89'	(b) (4), (b) (6)	22 Jan 2021 19:42:29

US3312197

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:01:02

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User entered 'mmHg'	System	22 Jan 2021 19:42:29

US3312197

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:01:02

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
	(b) (4)	
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Jan 2021 19:42:29

US3312197

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:01:02

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
	(b) (4)	
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Jan 2021 19:42:29

US3312197

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:01:02

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User entered empty.	System	22 Jan 2021 19:42:29
DataPoint set to visible.	System	22 Jan 2021 19:40:01

US3312197

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:02

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	22 Jan 2021 19:42:29

US3312197

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 19:42:29

US3312197

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
	(b) (4)	
User entered '12 Jan 2021'	(b) (4), (b) (6)	22 Jan 2021 19:42:29

US3312197

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
	(b) (4)	
User entered '14:55'	(b) (4), (b) (6)	22 Jan 2021 19:42:29

US3312197

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:02

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User entered '12 Jan 2021 14:55'	System	22 Jan 2021 19:42:29

US3312197

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
	(b) (4)	
User entered '98.7' F	(b) (4), (b) (6)	22 Jan 2021 19:42:29

US3312197

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
	(b) (4)	
User entered 'Oral (Oral)'	(b) (4), (b) (6)	22 Jan 2021 19:42:29

US3312197

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 19:42:29

US3312197

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
	(b) (4)	
User entered '75'	(b) (4), (b) (6)	22 Jan 2021 19:42:29

US3312197

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User entered 'bpm'	System	22 Jan 2021 19:42:29

US3312197

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:02

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
	(b) (4)	
User entered '14'	(b) (4), (b) (6)	22 Jan 2021 19:42:29

US3312197

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User entered 'breaths/min'	System	22 Jan 2021 19:42:29

US3312197

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
	(b) (4)	
User entered '117'	(b) (4), (b) (6)	22 Jan 2021 19:42:29

US3312197

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User entered 'mmHg'	System	22 Jan 2021 19:42:29

US3312197

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
	(b) (4)	
User entered '69'	(b) (4), (b) (6)	22 Jan 2021 19:42:29

US3312197

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:01:02

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User entered 'mmHg'	System	22 Jan 2021 19:42:29

US3312197

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:01:02

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 19:42:40

US3312197

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:01:02

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
	(b) (4)	
User entered '12 Jan 2021'	(b) (4), (b) (6)	22 Jan 2021 19:42:40

US3312197

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

Form: Exposure

Generated On: 09 Jun 2021 17:01:02

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 19:43:01

US3312197

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

Form: Exposure

Generated On: 09 Jun 2021 17:01:02

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 19:43:01

US3312197

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

Form: Exposure

Generated On: 09 Jun 2021 17:01:02

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 13:11:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 19:43:01

US3312197

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

Form: Exposure

Generated On: 09 Jun 2021 17:01:02

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User entered 'mRNA-1273'	System	22 Jan 2021 19:43:01
DataPoint set to visible.	System	22 Jan 2021 19:40:01

US3312197

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

Form: Exposure

Generated On: 09 Jun 2021 17:01:02

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
	(b) (4)	
User entered '12 Jan 2021'	(b) (4), (b) (6)	22 Jan 2021 19:43:01

US3312197

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

Form: Exposure

Generated On: 09 Jun 2021 17:01:02

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
	(b) (4)	
User entered '14:23'	(b) (4), (b) (6)	22 Jan 2021 19:43:01

US3312197

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

Form: Exposure

Generated On: 09 Jun 2021 17:01:02

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User entered '12 Jan 2021 14:23'	System	22 Jan 2021 19:43:01

US3312197

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

Form: Exposure

Generated On: 09 Jun 2021 17:01:02

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	22 Jan 2021 19:43:01

US3312197

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

Form: Exposure

Generated On: 09 Jun 2021 17:01:02

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User entered 'ONCE'	System	22 Jan 2021 19:43:01

US3312197

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

Form: Exposure

Generated On: 09 Jun 2021 17:01:02

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User entered 'INTRAMUSCULAR'	System	22 Jan 2021 19:43:01

US3312197

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:01:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 19:40:31

US3312197

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:01:02

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
	(b) (4)	
User entered '12 Jan 2021'	(b) (4), (b) (6)	22 Jan 2021 19:40:31

US3312197

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:01:02

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
	(b) (4)	
User entered '12:35'	(b) (4), (b) (6)	22 Jan 2021 19:40:31

US3312197

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:01:02

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User entered '12 Jan 2021 12:35'	System	22 Jan 2021 19:40:31

US3312197

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:01:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 19:40:43

US3312197

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:01:02

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
	(b) (4)	
User entered '12 Jan 2021'	(b) (4), (b) (6)	22 Jan 2021 19:40:43

US3312197

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:01:02

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
	(b) (4)	
User entered '12:34'	(b) (4), (b) (6)	22 Jan 2021 19:40:43

US3312197

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:01:02

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User entered '12 Jan 2021 12:34'	System	22 Jan 2021 19:40:43

US3312197

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

Form: Continuing

Generated On: 09 Jun 2021 17:01:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 19:40:49

US3312197

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

Form: Continuing

Generated On: 09 Jun 2021 17:01:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:11:23
User entered '1'	System	22 Jan 2021 19:40:49

US3312197

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:51:15
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Jan 2021 16:36:05

US3312197

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:51:15
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
	(b) (4)	
User entered '19 Jan 2021'	(b) (4), (b) (6)	27 Jan 2021 16:36:05

US3312197

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:51:15
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	27 Jan 2021 16:36:05

US3312197

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:01:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:51:15
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	27 Jan 2021 16:36:05

US3312197

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:51:15
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Jan 2021 16:36:14

US3312197

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:51:15
User entered 'I'	System	27 Jan 2021 16:36:14

US3312197

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:01:02

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:51:15
User entered 'I'	System	27 Jan 2021 16:36:14
DataPoint set to visible.	System	27 Jan 2021 16:36:14

US3312197

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:01:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:51
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered 'Yes (Y)'	(b) (4)	09 Feb 2021 22:40:54
	Karol Moore (b) (4)	
	(b) (4)	

US3312197

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:51
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered '09 Feb 2021'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Feb 2021 22:40:54

US3312197

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:01:02

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:51
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered 'Clinic (Clinic)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Feb 2021 22:40:54

US3312197

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:01:02

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:51
User entered 'OLD29'	System	09 Feb 2021 22:40:54

US3312197

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:51
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered 'Yes (Y)'	(b) (4)	09 Feb 2021 22:42:10
	Karol Moore (b) (4)	
	(b) (4)	

US3312197

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:51
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered '09 Feb 2021'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Feb 2021 22:42:10

US3312197

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:51
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered '12:32'	(b) (4)	09 Feb 2021 22:42:10
	Karol Moore (b) (4)	
	(b) (4)	

US3312197

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:51
User entered '09 Feb 2021 12:32'	System	09 Feb 2021 22:42:10

US3312197

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:51
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered '98.0' F	(b) (4)	09 Feb 2021 22:42:10
	Karol Moore (b) (4)	
	(b) (4)	

US3312197

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:51
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Feb 2021 22:42:10

US3312197

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:51
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered empty.	(b) (4)	09 Feb 2021 22:42:10
	Karol Moore (b) (4)	
	(b) (4)	

US3312197

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:51
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered '70'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Feb 2021 22:42:10

US3312197

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:51
User entered 'bpm'	System	09 Feb 2021 22:42:10

US3312197

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:51
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered '16'	(b) (4) Karol Moore (b) (4)	09 Feb 2021 22:42:10

US3312197

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:51
User entered 'breaths/min'	System	09 Feb 2021 22:42:10

US3312197

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:51
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered '123'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Feb 2021 22:42:10

US3312197

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:51
User entered 'mmHg'	System	09 Feb 2021 22:42:10

US3312197

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:51
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered '60'	(b) (4) Karol Moore (b) (4) (b) (4)	09 Feb 2021 22:42:10

US3312197

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:51
User entered 'mmHg'	System	09 Feb 2021 22:42:10

US3312197

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:51

US3312197

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:51

US3312197

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:01:02

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:51
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	09 Feb 2021 22:42:40

US3312197

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:01:02

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:51
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '09 Feb 2021'	(b) (4)	09 Feb 2021 22:42:40
	Karol Moore (b) (4)	
	(b) (4)	

US3312197

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:01:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:51
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	09 Feb 2021 22:43:00

US3312197

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:01:02

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:51
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '09 Feb 2021'	(b) (4) Karol Moore (b) (4)	09 Feb 2021 22:43:00

US3312197

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:01:02

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:51
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '12:45'	(b) (4)	09 Feb 2021 22:43:00
	Karol Moore (b) (4)	
	(b) (4)	

US3312197

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:01:02

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:16:51
User entered '09 Feb 2021 12:45'	System	09 Feb 2021 22:43:00

US3312197

Folder: Unscheduled 20 Aug 2020

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 17:01:02

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:39:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered '20 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 19:08:01

US3312197

Folder: Unscheduled 20 Aug 2020

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 17:01:02

[Physical Exam](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:39:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 19:08:01

US3312197

Folder: Unscheduled 20 Aug 2020

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 17:01:02

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:39:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered 'I'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 19:08:01

US3312197

Folder: Unscheduled 20 Aug 2020

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 17:01:02

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:39:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 19:08:01

US3312197

Folder: Unscheduled 20 Aug 2020

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 17:01:02

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:39:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 19:08:01

US3312197

Folder: Unscheduled 20 Aug 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:39:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 19:08:25

US3312197

Folder: Unscheduled 20 Aug 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:39:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered '20 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 19:08:25

US3312197

Folder: Unscheduled 20 Aug 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:39:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered '15:25'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 19:08:25

US3312197

Folder: Unscheduled 20 Aug 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:39:33
User entered '20 Aug 2020 15:25'	System	28 Aug 2020 19:08:25

US3312197

Folder: Unscheduled 20 Aug 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:39:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	28 Aug 2020 19:08:25

US3312197

Folder: Unscheduled 20 Aug 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:39:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 19:08:25

US3312197

Folder: Unscheduled 20 Aug 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:39:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered empty.	(b) (4)	28 Aug 2020 19:08:25
	Karol Moore (b) (4)	
	(b) (4)	

US3312197

Folder: Unscheduled 20 Aug 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:39:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 19:08:25

US3312197

Folder: Unscheduled 20 Aug 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:39:33
User entered 'bpm'	System	28 Aug 2020 19:08:25

US3312197

Folder: Unscheduled 20 Aug 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:39:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	28 Aug 2020 19:08:25

US3312197

Folder: Unscheduled 20 Aug 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:39:33
User entered 'breaths/min'	System	28 Aug 2020 19:08:25

US3312197

Folder: Unscheduled 20 Aug 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:39:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered '122'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 19:08:25

US3312197

Folder: Unscheduled 20 Aug 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:39:33
User entered 'mmHg'	System	28 Aug 2020 19:08:25

US3312197

Folder: Unscheduled 20 Aug 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:39:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered '69'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 19:08:25

US3312197

Folder: Unscheduled 20 Aug 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:39:33
User entered 'mmHg'	System	28 Aug 2020 19:08:25

US3312197

Folder: Unscheduled 20 Aug 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:39:33

US3312197

Folder: Unscheduled 20 Aug 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:39:33

US3312197

Folder: Unscheduled 24 Nov 2020

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 17:01:02

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:39:40
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered '24 Nov 2020'	(b) (4) Karol Moore (b) (4)	25 Nov 2020 21:35:37
	(b) (4)	

US3312197

Folder: Unscheduled 24 Nov 2020

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 17:01:02

[Physical Exam](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:39:40
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:35:37

US3312197

Folder: Unscheduled 24 Nov 2020

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 17:01:02

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:39:40
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered 'I'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:35:37

US3312197

Folder: Unscheduled 24 Nov 2020

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 17:01:02

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:39:40
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered '0'	(b) (4) Karol Moore (b) (4)	25 Nov 2020 21:35:37

US3312197

Folder: Unscheduled 24 Nov 2020

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 17:01:02

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:39:40
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:35:37

US3312197

Folder: Unscheduled 24 Nov 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:39:44
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:36:26

US3312197

Folder: Unscheduled 24 Nov 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:39:44
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered '24 Nov 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:36:26

US3312197

Folder: Unscheduled 24 Nov 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:39:44
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered '14:09'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:36:26

US3312197

Folder: Unscheduled 24 Nov 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:39:44
User entered '24 Nov 2020 14:09'	System	25 Nov 2020 21:36:26

US3312197

Folder: Unscheduled 24 Nov 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:39:44
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	25 Nov 2020 21:36:26

US3312197

Folder: Unscheduled 24 Nov 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:39:44
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	25 Nov 2020 21:36:26

US3312197

Folder: Unscheduled 24 Nov 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:39:44
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered empty.	(b) (4)	25 Nov 2020 21:36:26
	Karol Moore (b) (4)	
	(b) (4)	

US3312197

Folder: Unscheduled 24 Nov 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:39:44
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	25 Nov 2020 21:36:26

US3312197

Folder: Unscheduled 24 Nov 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:39:44
User entered 'bpm'	System	25 Nov 2020 21:36:26

US3312197

Folder: Unscheduled 24 Nov 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:39:44
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered '20'	(b) (4) Karol Moore (b) (4)	25 Nov 2020 21:36:26

US3312197

Folder: Unscheduled 24 Nov 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:39:44
User entered 'breaths/min'	System	25 Nov 2020 21:36:26

US3312197

Folder: Unscheduled 24 Nov 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:39:44
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	25 Nov 2020 21:36:26

US3312197

Folder: Unscheduled 24 Nov 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:39:44
User entered 'mmHg'	System	25 Nov 2020 21:36:26

US3312197

Folder: Unscheduled 24 Nov 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:39:44
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	25 Nov 2020 21:36:26

US3312197

Folder: Unscheduled 24 Nov 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:39:44
User entered 'mmHg'	System	25 Nov 2020 21:36:26

US3312197

Folder: Unscheduled 24 Nov 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:39:44

US3312197

Folder: Unscheduled 24 Nov 2020

Form: Vital Signs

Generated On: 09 Jun 2021 17:01:02

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:39:44

US3312197

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:01:02

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:25:49
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:50:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:15
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Aug 2020 18:44:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Aug 2020 18:44:02
User entered 'Yes (Y)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:44:02
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Aug 2020 18:43:58
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:43:58

US3312197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:02

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:24:57

US3312197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:02

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:24:57
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:17:50
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Exacerbation of anxiety - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 21:04:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 21:04:41
Data point term sent to Coder	System	28 Aug 2020 18:45:15
User entered 'anxiety exacerbation'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:45:06

US3312197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:02

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:24:57
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:17:57
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:45:06

US3312197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:02

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:24:57
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:18:04
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:45:06

US3312197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:02

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:24:57
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:18:20
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:45:06

US3312197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:24:57
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:18:26
User entered '25 Aug 2020'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:45:06

US3312197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:02

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:24:57
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:18:29
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:45:06

US3312197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:02

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:24:57
User entered empty.	System	28 Aug 2020 18:45:06

US3312197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:02

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:24:57
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:18:33
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:45:06

US3312197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:02

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:24:57
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:18:36
User entered '25 Aug 2020'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:45:06

US3312197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:02

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:24:57
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:18:39
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:45:06

US3312197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:02

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:24:57
User entered empty.	System	28 Aug 2020 18:45:06

US3312197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:02

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:24:57
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:18:45
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:45:06

US3312197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:02

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:24:57
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:19:07
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:45:06

US3312197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:02

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:24:57
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:33:35
User entered '0'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:45:06

US3312197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:02

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:24:57
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:33:38
User entered '0'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:45:06

US3312197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:24:57
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:35:49
User entered '0'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:45:06

US3312197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:02

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:24:57
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:35:55
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:45:06

US3312197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:02

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:24:57
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:36:33
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:45:06

US3312197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:02

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:24:57
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:36:35
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:45:06

US3312197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:02

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:24:57
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:36:37
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:45:06

US3312197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:24:57
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:36:39
User entered '0'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:45:06

US3312197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:24:57
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:36:41
User entered '0'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:45:06

US3312197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:02

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:24:57
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:36:44
User entered '0'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:45:06

US3312197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:02

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:24:57
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:37:11
User entered 'Not Related (NOT RELATED)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:45:06

US3312197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:02

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:24:57
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:37:12
User entered 'Not Related (NOT RELATED)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:45:06

US3312197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:02

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:24:57
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:37:20
User entered 'None (NONE)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:45:06

US3312197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:02

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:24:57
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:37:39
User entered 'l'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:45:06

US3312197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:02

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:24:57
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:37:41
User entered '0'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:45:06

US3312197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:02

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:24:57
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:37:43
User entered '0'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:45:06

US3312197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:02

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:24:57
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:37:50
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:45:06

US3312197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:02

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:24:57
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:37:52
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:45:06

US3312197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:02

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:24:57
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:37:54
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:45:06

US3312197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:02

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:24:57
User entered '0'	System	28 Aug 2020 18:45:06

US3312197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:02

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:24:57
User entered 'I'	System	28 Aug 2020 18:45:06

US3312197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:01:02

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:24:57

US3312197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:02

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:02
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:37:45
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 16:17:42

US3312197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:02

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User closed query 'PV Query: Please confirm if the event of "Exacerbation of left cervical radiculopathy" met any seriousness reporting criteria.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:07:16
Query 'PV Query: Please confirm if the event of "Exacerbation of left cervical radiculopathy" met any seriousness reporting criteria.' answered with 'confirmed not an SAE' (Site from Safety).	(b) (4), (b) (6)	17 Mar 2021 19:07:02
User opened query 'PV Query: Please confirm if the event of "Exacerbation of left cervical radiculopathy" met any seriousness reporting criteria.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 16:14:56
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 16:40:42
User closed query 'Per DM CLR: Please review AE and please update to specify the location of Left Radiculopathy. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 18:30:51
User coded data point as SOC: Nervous system disorders, HLG: Spinal cord and nerve root disorders, HLT: Cervical spinal cord and nerve root disorders, PT: Cervical radiculopathy, LLT: Cervical radiculopathy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 23:26:27
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 23:26:27
Query 'Per DM CLR: Please review AE and please update to specify the location of Left Radiculopathy. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify. ' answered with 'Updated. Thank you. ' (Site from DM).	Heather Barker (b) (4) (b) (4)	22 Oct 2020 23:13:39
Data point term sent to Coder	System	22 Oct 2020 23:13:16
Coding entries removed.	Heather Barker (b) (4) (b) (4)	22 Oct 2020 23:13:09

US3312197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:02

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'EXACERBATION OF LEFT CERVICAL RADICULOPATHY' reason for change: Data Entry Error	Heather Barker (b) (4)	22 Oct 2020 23:13:09
User opened query 'Per DM CLR: Please review AE and please update to specify the location of Left Radiculopathy. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 05:26:34
User coded data point as SOC: Nervous system disorders, HLGT: Spinal cord and nerve root disorders, HLT: Spinal cord and nerve root disorders NEC, PT: Radiculopathy, LLT: Radiculopathy - version MedDRA\\23.0.	Coder Import (b) (4)	22 Sep 2020 05:13:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	22 Sep 2020 05:13:49
Data point term sent to Coder	System	21 Sep 2020 22:14:49
User entered 'EXACERBATION OF LEFT RADICULOPATHY'	Karol Moore (b) (4)	21 Sep 2020 22:14:09

US3312197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:02

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:40:47
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:14:09

US3312197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:02

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:40:50
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:14:09

US3312197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:02

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:40:52
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:14:09

US3312197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:41:09
User entered '06 Sep 2020'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:14:09

US3312197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:02

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:41:11
User entered empty.	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:14:09

US3312197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:02

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:02
User entered empty.	System	21 Sep 2020 22:14:09

US3312197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:02

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:41:13
User entered 'No (N)' reason for change: Data Entry Error	Heather Barker (b) (4) (b) (4)	22 Oct 2020 23:19:33
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:14:09

US3312197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:02

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:41:16
User entered '09 Oct 2020' reason for change: Data Entry Error	Heather Barker (b) (4) (b) (4)	22 Oct 2020 23:19:33
User entered empty.	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:14:09

US3312197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:02

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:41:18
User entered empty.	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:14:09

US3312197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:02

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:02
User entered empty.	System	21 Sep 2020 22:14:09

US3312197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:02

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:41:23
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:14:09

US3312197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:02

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:41:28
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:14:09

US3312197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:02

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:41:31
User entered '0'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:14:09

US3312197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:02

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:41:34
User entered '0'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:14:09

US3312197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:41:37
User entered '0'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:14:09

US3312197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:02

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:41:40
User entered empty.	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:14:09

US3312197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:02

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:41:55
User entered empty.	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:14:09

US3312197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:02

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:41:57
User entered empty.	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:14:09

US3312197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:02

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:42:02
User entered empty.	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:14:09

US3312197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:42:04
User entered '0'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:14:09

US3312197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:42:06
User entered '0'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:14:09

US3312197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:02

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:42:07
User entered '0'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:14:09

US3312197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:02

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:42:29
Query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	25 Sep 2020 13:21:32
User opened query 'Action taken with investigational System product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).		21 Sep 2020 22:14:09
User entered 'Not Related (NOT RELATED)'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:14:09

US3312197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:02

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:42:31
User entered 'Not Related (NOT RELATED)'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:14:09

US3312197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:02

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:47:20
User closed query 'Per CDM re-query: Please consider entering "Dosing discontinuation" form because subject withdrawn IP. Thank you!' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 07:33:03
Query 'Per CDM re-query: Please consider entering "Dosing discontinuation" form because subject withdrawn IP. Thank you!' answered with 'Dosing discontinuation has now been entered. Thank you. ' (Site from DM).	Heather Barker (b) (4) (b) (4)	22 Oct 2020 23:17:34
User opened query 'Per CDM re-query: Please consider entering "Dosing discontinuation" form because subject withdrawn IP. Thank you!' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 08:20:48
User closed query 'Per CDM: Since subject withdrawn from the study, then please kindly consider completing "End of Study" forms. Thank you!' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 08:20:48
Query 'Per CDM: Since subject withdrawn from the study, then please kindly consider completing "End of Study" forms. Thank you!' answered with 'IP withdrawn. Subject not withdrawn, will continue to follow for safety.' (Site from DM).	Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:35:23
User opened query 'Per CDM: Since subject withdrawn from the study, then please kindly consider completing "End of Study" forms. Thank you!' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 11:54:38
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:14:09

US3312197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:02

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:47:30
User entered '0'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:14:09

US3312197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:02

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:47:50
User entered 'l'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:14:09

US3312197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:02

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:47:52
User entered '0'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:14:09

US3312197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:02

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:48:00
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Heather Barker (b) (4) (b) (4)	22 Oct 2020 23:19:33
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:14:09

US3312197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:02

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:48:02
User entered empty.	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:14:09

US3312197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:02

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:48:04
User entered empty.	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:14:09

US3312197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:02

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:02
User entered '0'	System	21 Sep 2020 22:14:09

US3312197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:02

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:02
User entered 'I'	System	21 Sep 2020 22:14:09

US3312197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:01:02

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:25:02

US3312197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:02

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:48:11
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:18
User entered 'USA-US300-2020-mRNA-1273-P301000015'	System	01 Dec 2020 13:42:15
User entered 'New'	(b) (4), (b) (6)	01 Dec 2020 13:42:15

US3312197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:02

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User closed query 'Per MM, please confirm if the subject received second dose of IP. If not, please update the "action taken with IP", as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Jan 2021 06:15:20
Query 'Per MM, please confirm if the subject received second dose of IP. If not, please update the "action taken with IP", as appropriate.' answered with 'Did not receive Dose 2 but not due to this AE' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 22:55:48
User opened query 'Per MM, please confirm if the subject received second dose of IP. If not, please update the "action taken with IP", as appropriate.' (Site from DM).	(b) (4), (b) (6)	31 Dec 2020 08:28:55
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 16:48:34
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Pneumonia, LLT: Pneumonia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	01 Dec 2020 01:44:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	01 Dec 2020 01:44:01
Data point term sent to Coder	System	01 Dec 2020 01:42:37
User entered 'pneumonia'	(b) (4), (b) (6)	01 Dec 2020 01:42:15

US3312197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:02

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:48:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Dec 2020 01:42:15

US3312197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:02

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:48:45
User entered 'No (N)'	(b) (4), (b) (6)	01 Dec 2020 01:42:15

US3312197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:02

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:48:48
User entered 'No (N)'	(b) (4), (b) (6)	01 Dec 2020 01:42:15

US3312197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:48:53
User entered '22 Nov 2020'	(b) (4), (b) (6)	01 Dec 2020 01:42:15

US3312197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:02

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:48:56
User entered empty.	(b) (4), (b) (6)	01 Dec 2020 01:42:15

US3312197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:02

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Dec 2020 01:42:15

US3312197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:02

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:48:59
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	17 Dec 2020 22:12:28
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 22:12:28
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	17 Dec 2020 22:12:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Dec 2020 01:42:15

US3312197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:02

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4)	23 Dec 2020 14:58:01
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	23 Dec 2020 14:58:01
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	23 Dec 2020 14:57:41
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	22 Dec 2020 19:23:10
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	22 Dec 2020 19:23:10
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	22 Dec 2020 19:22:04
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 16:49:01
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	17 Dec 2020 22:12:14
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	17 Dec 2020 22:12:14
User entered '09 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 22:12:14
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	17 Dec 2020 22:11:55
User entered empty.	(b) (4), (b) (6)	01 Dec 2020 01:42:15

US3312197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:02

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:49:05
User entered empty.	(b) (4), (b) (6)	01 Dec 2020 01:42:15

US3312197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:02

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' canceled (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 17:36:48
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 16:55:05
User entered empty.	System	01 Dec 2020 01:42:15

US3312197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:02

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:49:08
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	01 Dec 2020 01:42:15

US3312197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:02

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:49:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Dec 2020 01:42:15

US3312197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:02

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:53:03
User entered '0'	(b) (4), (b) (6)	01 Dec 2020 01:42:15

US3312197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:02

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:53:18
User entered '0'	(b) (4), (b) (6)	01 Dec 2020 01:42:15

US3312197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:53:24
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	02 Dec 2020 02:45:35
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'ongoing at this time' (Site from System).	(b) (4), (b) (6)	01 Dec 2020 01:42:34
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	01 Dec 2020 01:42:15
User entered 'I'	(b) (4), (b) (6)	01 Dec 2020 01:42:15

US3312197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:02

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:53:34
User entered '28 Nov 2020'	(b) (4), (b) (6)	01 Dec 2020 01:42:15

US3312197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:02

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:55:00
User closed query 'PV Query: Please provide the hospital discharge date when available. ' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 18:23:50
Query 'PV Query: Please provide the hospital discharge date when available. ' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 21:01:01
User entered '01 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Dec 2020 21:00:54
User opened query 'PV Query: Please provide the hospital discharge date when available. ' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 16:40:15
User entered empty.	(b) (4), (b) (6)	01 Dec 2020 01:42:15

US3312197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:02

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:55:25
User entered 'No (N)'	(b) (4), (b) (6)	01 Dec 2020 01:42:15

US3312197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:02

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:55:28
User entered empty.	(b) (4), (b) (6)	01 Dec 2020 01:42:15

US3312197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:18
User entered '0'	(b) (4), (b) (6)	01 Dec 2020 01:42:15

US3312197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:20
User entered '0'	(b) (4), (b) (6)	01 Dec 2020 01:42:15

US3312197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:02

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:56:58
User entered '0'	(b) (4), (b) (6)	01 Dec 2020 01:42:15

US3312197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:02

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:57:09
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Dec 2020 21:54:55
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	01 Dec 2020 01:42:15

US3312197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:02

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:57:11
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Dec 2020 21:54:55
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	01 Dec 2020 01:42:15

US3312197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:02

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:37:58
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User closed query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in dosing discontinuation if applicable. Review and update. Else, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Feb 2021 14:29:30
Query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in dosing discontinuation if applicable. Review and update. Else, clarify.	(b) (4), (b) (6)	17 Feb 2021 00:14:18
' answered with 'updated' (Site from DM).		
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Feb 2021 00:14:12
User opened query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in dosing discontinuation if applicable. Review and update. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 04:31:03
User closed query 'PV Query: Since the subject did not receive both doses. Please consider updating action taken to the study drug to Dose delayed or Dose withdrawn if applicable.' (Site from Safety).	(b) (4), (b) (6)	02 Feb 2021 15:56:23
Query 'PV Query: Since the subject did not receive both doses. Please consider updating action taken to the study drug to Dose delayed or Dose withdrawn if applicable.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	02 Feb 2021 00:56:46
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Feb 2021 00:56:38
User opened query 'PV Query: Since the subject did not receive both doses. Please consider updating action taken to the study drug to Dose delayed or Dose withdrawn if applicable.' (Site from Safety).	(b) (4), (b) (6)	20 Jan 2021 12:21:19
DataPoint Un-verified.	(b) (4), (b) (6)	11 Jan 2021 22:56:07

PRODUCTION RELEASE (v12.003
EAB) (1725)

2249 of 3104

US3312197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:02

Action taken with investigational product

Audit	User	Time (GMT)
User entered 'None (NONE)' reason for change: Data Entry Error DataPoint Verified.	(b) (4), (b) (6)	11 Jan 2021 22:56:07
	(b) (4), (b) (6)	22 Dec 2020 16:57:21
User closed query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn. ' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 18:23:56
Query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn. ' answered with 'No further vaccines per protocol schedule' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 21:00:19
User opened query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn. ' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 16:39:09
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	01 Dec 2020 01:42:15

US3312197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:02

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:57:24
User entered '0'	(b) (4), (b) (6)	01 Dec 2020 01:42:15

US3312197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:02

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:57:26
User entered 'I'	(b) (4), (b) (6)	01 Dec 2020 01:42:15

US3312197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:02

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:57:28
User entered '0'	(b) (4), (b) (6)	01 Dec 2020 01:42:15

US3312197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:02

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:38:28
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User closed query 'Source states recovering. Please review and reconcile.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:47:20
Query 'Source states recovering. Please review and reconcile.' answered with 'SOURCE UPDATED' (Site from CRA).	Karol Moore (b) (4) (b) (4)	23 Dec 2020 14:58:37
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Karol Moore (b) (4) (b) (4)	23 Dec 2020 14:58:01
Data Entry Error		
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change:	Karol Moore (b) (4) (b) (4)	23 Dec 2020 14:57:41
Data Entry Error		
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Karol Moore (b) (4) (b) (4)	22 Dec 2020 19:23:10
Data Entry Error		
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change:	Karol Moore (b) (4) (b) (4)	22 Dec 2020 19:22:04
Data Entry Error		
User opened query 'Source states recovering. Please review and reconcile.' (Site from CRA).	(b) (4), (b) (6)	22 Dec 2020 16:58:06
DataPoint Un-verified.	(b) (4), (b) (6)	22 Dec 2020 16:57:42
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 16:57:36
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	18 Dec 2020 19:37:17
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	17 Dec 2020 22:12:36
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4), (b) (6)	17 Dec 2020 22:11:55
Data Entry Error		

US3312197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:02

[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. ' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 17:00:31
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	01 Dec 2020 01:42:15

US3312197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:02

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:38:30
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 01:42:15

US3312197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:02

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User closed query 'Per DM CLR: Narrative = LABS (INCLUDING BNP, D-DIMER, CBC, METABOLIC PROFILE). However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Feb 2021 14:29:38
Query 'Per DM CLR: Narrative = LABS (INCLUDING BNP, D-DIMER, CBC, METABOLIC PROFILE). However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Not procedures-diagnostic only-NA ON CM CRF' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 00:14:39
User opened query 'Per DM CLR: Narrative = LABS (INCLUDING BNP, D-DIMER, CBC, METABOLIC PROFILE). However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 04:31:20
User closed query 'PV Query: Please provide echocardiogram results.' (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 17:01:24
Query 'PV Query: Please provide echocardiogram results.' answered with 'no reference of ECHO, only Electrocardiogram which medical record was sent to safety 08Dec2020 ' (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 18:58:11
User opened query 'PV Query: Please provide echocardiogram results.' (Site from Safety).	(b) (4), (b) (6)	20 Jan 2021 12:20:59
User closed query 'PV Query: Please clarify whether subject received one or two doses of the blinded study vaccination. If 2 doses were administered, please provide dates. ' (Site from Safety).	(b) (4), (b) (6)	12 Jan 2021 16:47:03
User closed query 'PV Query: Please provide the results of oxygen saturation at hospital admission and echocardiogram results.' (Site from Safety).	(b) (4), (b) (6)	12 Jan 2021 16:46:59
User closed query 'Per DM CLR: SAE Narrative = EKG, LABS (INCLUDING BNP, D-DIMER, CBC, METABOLIC PROFILE) AND CXR. However, these were not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 06:17:08

PRODUCTION RELEASE (v12.003
EAB) (1725)

2257 of 3104

US3312197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:02

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: SAE Narrative = TREATMENT INCLUDED O2 PER NASAL CANNULA TITRATED TO SATS, SOLUMEDROL AND IV BENADRYL X 1, AND ANTIBIOTIC TREATMENT WITH CEFTRIAZONE AND AZITHROMYCIN. However, these were not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 06:17:06
Query 'Per DM CLR: SAE Narrative = TREATMENT INCLUDED O2 PER NASAL CANNULA TITRATED TO SATS, SOLUMEDROL AND IV BENADRYL X 1, AND ANTIBIOTIC TREATMENT WITH CEFTRIAZONE AND AZITHROMYCIN. However, these were not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 23:33:28
Query 'Per DM CLR: SAE Narrative = EKG, LABS (INCLUDING BNP, D-DIMER, CBC, METABOLIC PROFILE) AND CXR. However, these were not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'EKG and CXR updated on COn procedure log; however labs not entered as date already in narrative and not needed per PI' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 23:13:38
Query 'PV Query: Please provide the results of oxygen saturation at hospital admission and echocardiogram results.' answered with 'per medical records >90%' (Site from Safety).	(b) (4), (b) (6)	11 Jan 2021 22:58:27
Query 'PV Query: Please clarify whether subject received one or two doses of the blinded study vaccination. If 2 doses were administered, please provide dates. ' answered with 'Received only 1' (Site from Safety).	(b) (4), (b) (6)	11 Jan 2021 22:57:01

US3312197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:02

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: SAE Narrative = EKG, LABS (INCLUDING BNP, D-DIMER, CBC, METABOLIC PROFILE) AND CXR. However, these were not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 01:12:45
User opened query 'Per DM CLR: SAE Narrative = TREATMENT INCLUDED O2 PER NASAL CANNULA TITRATED TO SATS, SOLUMEDROL AND IV BENADRYL X 1, AND ANTIBIOTIC TREATMENT WITH CEFTRIAZONE AND AZITHROMYCIN. However, these were not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 01:12:39
User opened query 'PV Query: Please clarify whether subject received one or two doses of the blinded study vaccination. If 2 doses were administered, please provide dates. ' (Site from Safety).	(b) (4), (b) (6)	29 Dec 2020 19:00:20
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 17:05:03
User opened query 'PV Query: Please provide the results of oxygen saturation at hospital admission and echocardiogram results.' (Site from Safety).	(b) (4), (b) (6)	22 Dec 2020 15:47:11

US3312197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:02

[Narrative](#)

Audit	User	Time (GMT)
User entered 'DAY 1 ILLNESS VISIT WAS ON 24NOV2020 FOR MODERATE SOB, DIFFICULTY BREATHING, COUGH, FATIGUE, H/A, NASAL CONGESTION, RUNNY NOSE, DIARRHEA, SORE THROAT, AND MILD NAUSEA ONSET 22NOV2020.AUGMENTIN FOR COVID-NEGATIVE PNEUMONIA PRESCRIBED AT URGENT CARE VISIT 24NOV2020.PREVIOUSLY UNREPORTED H/O ANOSMIA SINCE 1969 AND SLEEP APNEA SINCE 1990 WERE REVEALED.ON 28NOV2020 SUBJ WENT TO ER FOR WORSENING SOB; ADMITTED FOR PNEUMONIA WITH O2 REQUIREMENT, STARTED ON O2 AND IV ANTIBIOTICS.ON 29NOV2020 O2SAT WAS 95% ON 1L O2. ON 30NOV2020 SUBJECT HAD NEGATIVE COVID TEST RESULT IN HOSPITAL, HAD MARKEDLY IMPROVED SYMPTOMS, HAD 92% SAT ON ROOM AIR, AND SOUNDED GOOD ON PHONE CALL.EXPECTED DISCHARGE DATE 01DEC2020F/U BASED ON MED RECS REVIEW AND PHONE CALL WITH SUBJ 07DEC2020. HOSPITAL DISCHARGE 01DEC2020 WITH O2 SATS 94% ON RA, NORMAL VITALS, MARKEDLY IMPROVED SYMPTOMS, AND CLEAR LUNG SOUNDS BILATERALLY AFTER TREATMENT FOR COVID-NEGATIVE PNEUMONIA WITHOUT EVIDENCE OF CHF, AFIB, NEW HEART ABNORMALITY, OR CLOTTING PER PHYSICAL EXAM, EKG, LABS (INCLUDING BNP, D-DIMER, CBC, METABOLIC PROFILE) AND CXR (BILATERAL PATCHY INFILTRATES). TREATMENT INCLUDED O2 PER NASAL CANNULA TITRATED TO SATS, SOLUMEDROL AND IV BENADRYL X 1, AND ANTIBIOTIC TREATMENT WITH CEFTRIAZONE AND AZITHROMYCIN WHICH WAS COMPLETED WHILE IN HOSPITAL. AT PHONE CALL, SUBJECT REPORTED IMPROVING SHORTNESS	(b) (4), (b) (6)	17 Dec 2020 22:13:30

US3312197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:02

[Narrative](#)

Audit	User	Time (GMT)
OF AIR, COUGH, FATIGUE, AND CONGESTION. WILL CONTINUE TO FOLLOW.final follow up with PCP		
09Dec2020-lungs clear, no further follow up or CMs.		
AE CLOSED' reason for change: Data Entry Error		
User closed query 'IQVIA medical query: Please clarify the rationale why the event is assessed as Not applicable to the IP and study procedure.' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 18:24:43
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 18:24:18
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 18:24:13
User closed query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 18:24:10
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 18:24:05
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'updated CM Log' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 22:03:06

US3312197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:02

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' answered with 'sent via email with discharge summary; including relevant CXR' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 22:02:31
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' answered with 'Sent via email' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 22:02:00
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event' answered with 'medical history of: HTN, Afib, MI, hyperlipidemia, sleep apnea, age 69' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 22:00:33
Query 'IQVIA medical query: Please clarify the rationale why the event is assessed as Not applicable to the IP and study procedure.' answered with 'error, updated to Not related' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 21:55:25

US3312197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:02

[Narrative](#)

Audit	User	Time (GMT)
User entered 'DAY 1 ILLNESS VISIT WAS ON 24NOV2020 FOR MODERATE SOB, DIFFICULTY BREATHING, COUGH, FATIGUE, H/A, NASAL CONGESTION, RUNNY NOSE, DIARRHEA, SORE THROAT, AND MILD NAUSEA ONSET 22NOV2020.AUGMENTIN FOR COVID-NEGATIVE PNEUMONIA PRESCRIBED AT URGENT CARE VISIT 24NOV2020.PREVIOUSLY UNREPORTED H/O ANOSMIA SINCE 1969 AND SLEEP APNEA SINCE 1990 WERE REVEALED.ON 28NOV2020 SUBJ WENT TO ER FOR WORSENING SOB; ADMITTED FOR PNEUMONIA WITH O2 REQUIREMENT, STARTED ON O2 AND IV ANTIBIOTICS.ON 29NOV2020 O2SAT WAS 95% ON 1L O2. ON 30NOV2020 SUBJECT HAD NEGATIVE COVID TEST RESULT IN HOSPITAL, HAD MARKEDLY IMPROVED SYMPTOMS, HAD 92% SAT ON ROOM AIR, AND SOUNDED GOOD ON PHONE CALL.EXPECTED DISCHARGE DATE 01DEC2020F/u based on med recs review and phone call with subj 07Dec2020. Hospital discharge 01Dec2020 with O2 sats 94% on RA, normal vitals, markedly improved symptoms, and clear lung sounds bilaterally after treatment for Covid-negative pneumonia without evidence of CHF, afib, new heart abnormality, or clotting per physical exam, ekg, labs (including BNP, d-dimer, cbc, metabolic profile) and CXR (bilateral patchy infiltrates). Treatment included O2 per nasal cannula titrated to sats, solumedrol and iv benadryl x 1, and antibiotic treatment with ceftriazone and azithromycin which was completed while in hospital. At phone call, subject reported improving shortness of air, cough, fatigue, and congestion. Will continue to follow.'	(b) (4), (b) (6)	08 Dec 2020 20:59:25
reason for change: Data Entry Error User opened query 'IQVIA medical query: Please clarify the rationale why the event is assessed as Not applicable to the IP and study procedure.' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 17:02:24

US3312197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:02

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 17:01:53
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 17:00:00
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 16:59:37
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' canceled (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 16:54:13
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 16:49:39
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 16:48:03

US3312197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:02

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Day 1 illness visit was on 24NOV2020 for moderate sob, difficulty breathing, cough, fatigue, h/a, nasal congestion, runny nose, diarrhea, sore throat, and mild nausea onset 22NOV2020.Augmentin for Covid-negative pneumonia prescribed at urgent care visit 24NOV2020.Previously unreported h/o anosmia since 1969 and sleep apnea since 1990 were revealed.On 28NOV2020 subj went to ER for worsening sob; admitted for pneumonia with O2 requirement, started on O2 and iv antibiotics.On 29NOV2020 O2sat was 95% on 1L O2. On 30Nov2020 subject had negative Covid test result in hospital, had markedly improved symptoms, had 92% sat on room air, and sounded good on phone call.Expected discharge date 01Dec2020'	(b) (4), (b) (6)	01 Dec 2020 01:42:15

US3312197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:02

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Dec 2020 01:42:15

US3312197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:02

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Dec 2020 01:42:15

US3312197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:01:02

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	01 Dec 2020 01:42:15

US3312197

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:01:02

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:39:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Hyperglycaemic conditions NEC, PT: Glucose tolerance impaired, LLT: Pre-diabetes - version MedDRA\\23.0.	Coder Import (b) (4)	05 Jan 2021 17:01:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Jan 2021 17:01:30
Data point term sent to Coder	System	05 Jan 2021 16:45:22
User entered 'pre-diabetes'	(b) (4), (b) (6)	05 Jan 2021 16:45:11

US3312197

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:01:02

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:39:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:45:11

US3312197

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:01:02

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:39:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:45:11

US3312197

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:01:02

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:39:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:45:11

US3312197

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:39:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '28 Dec 2020'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:45:11

US3312197

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:01:02

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:39:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:45:11

US3312197

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:01:02

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Jan 2021 16:45:11

US3312197

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:01:02

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:39:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	11 Jan 2021 22:54:02
User entered 'No (N)'	(b) (4), (b) (6)	05 Jan 2021 16:45:11

US3312197

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:01:02

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:39:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	(b) (4)	11 Jan 2021 22:54:02
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	05 Jan 2021 16:45:11
User entered empty.	(b) (4), (b) (6)	05 Jan 2021 16:45:11

US3312197

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:01:02

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:39:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:45:11

US3312197

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:01:02

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Jan 2021 16:45:11

US3312197

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:01:02

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:39:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:45:11

US3312197

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:01:02

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:39:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:45:11

US3312197

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:01:02

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:39:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:45:11

US3312197

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:01:02

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:39:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:45:11

US3312197

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:01:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:39:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:45:11

US3312197

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:01:02

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:39:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:45:11

US3312197

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:01:02

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:39:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:45:11

US3312197

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:01:02

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:39:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:45:11

US3312197

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:01:02

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:39:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:45:11

US3312197

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:01:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:39:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:45:11

US3312197

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:01:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:39:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:45:11

US3312197

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:01:02

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:39:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:45:11

US3312197

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:01:02

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:39:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:45:11

US3312197

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:01:02

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:39:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:45:11

US3312197

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:01:02

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:39:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:45:11

US3312197

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:01:02

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:39:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:45:11

US3312197

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:01:02

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:39:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'I'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:45:11

US3312197

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:01:02

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:39:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:45:11

US3312197

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:01:02

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:39:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:45:11

US3312197

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:01:02

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:39:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:45:11

US3312197

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:01:02

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:39:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:45:11

US3312197

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:01:02

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Jan 2021 16:45:11

US3312197

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:01:02

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Jan 2021 16:45:11

US3312197

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:01:02

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:39:24
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
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 herniation - version MedDRA\\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Apr 2021 13:28:47
Data point term sent to Coder	(b) (4)	
User entered 'SPINAL DISC HERNIATION'	Coder Import (b) (4)	16 Apr 2021 13:28:47
	(b) (4)	
	System	16 Apr 2021 13:28:00
	(b) (4), (b) (6)	16 Apr 2021 13:27:40

US3312197

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:01:02

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:39:24
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:27:40

US3312197

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:01:02

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:39:24
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:27:40

US3312197

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:01:02

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:39:24
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:27:40

US3312197

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:39:24
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User entered '05 Apr 2021'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:27:40

US3312197

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:01:02

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:39:24
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:27:40

US3312197

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:01:02

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 13:27:40

US3312197

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:01:02

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:39:24
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:27:40

US3312197

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:01:02

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:39:24
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:27:40

US3312197

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:01:02

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:39:24
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:27:40

US3312197

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:01:02

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 13:27:40

US3312197

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:01:02

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:39:24
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:27:40

US3312197

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:01:02

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:39:24
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:27:40

US3312197

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:01:02

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:39:24
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:27:40

US3312197

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:01:02

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:39:24
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:27:40

US3312197

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:01:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:39:24
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:27:40

US3312197

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:01:02

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:39:24
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:27:40

US3312197

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:01:02

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:39:24
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:27:40

US3312197

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:01:02

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:39:24
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:27:40

US3312197

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:01:02

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:39:24
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:27:40

US3312197

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:01:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:39:24
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:27:40

US3312197

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:01:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:39:24
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:27:40

US3312197

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:01:02

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:39:24
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:27:40

US3312197

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:01:02

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:39:24
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:27:40

US3312197

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:01:02

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:39:24
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:27:40

US3312197

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:01:02

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:39:24
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:27:40

US3312197

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:01:02

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:39:24
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:27:40

US3312197

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:01:02

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:39:24
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User entered 'I'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:27:40

US3312197

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:01:02

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:39:24
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:27:40

US3312197

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:01:02

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:39:24
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:27:40

US3312197

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:01:02

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:39:24
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:27:40

US3312197

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:01:02

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:39:24
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:27:40

US3312197

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:01:02

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	16 Apr 2021 13:27:40

US3312197

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:01:02

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 13:27:40

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:25:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User closed query 'Per ETRTR: Medication for SAE "Pneumonia" reported in Narrative is not present on the Concomitant Medication. Please update.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:11:05
Query 'Per ETRTR: Medication for SAE "Pneumonia" reported in Narrative is not present on the Concomitant Medication. Please update.' answered with 'UPDATED' (Site from CRA).	Karol Moore (b) (4) (b) (4)	23 Dec 2020 15:02:45
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 17:11:22
User opened query 'Per ETRTR: Medication for SAE "Pneumonia" reported in Narrative is not present on the Concomitant Medication. Please update.' (Site from CRA).	(b) (4), (b) (6)	10 Dec 2020 18:19:23
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:37:41

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:01:02

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:12:23
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN HYDROCHLORIDE, PRODUCTSYNONYM: TAMULOSIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 18:39:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 18:39:41
Data point term sent to Coder	System	28 Aug 2020 18:38:59
User entered 'tamulosin'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:38:23

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:01:02

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:12:55
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:38:23

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:01:02

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:13:19
User entered 'Benign prostatic hyperplasia'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:38:23

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:01:02

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:13:38
User entered '0.4'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:38:23

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:01:02

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:13:40
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:38:23

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:01:02

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:13:41
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:38:23

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:01:02

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:13:45
User entered 'once daily (QD)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:38:23

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:01:02

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:13:47
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:38:23

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:01:02

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:13:51
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:38:23

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:01:02

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:13:53
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:38:23

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:13:59
User entered 'un UNK 2018'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:38:23

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:01:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:14:00
User entered '0'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:38:23

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:01:02

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:14:06
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:38:23

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:01:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:14:13
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:38:23

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:01:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:14:18
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:38:23

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:01:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 18:38:23

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:01:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 18:38:23

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:01:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Aug 2020 18:38:23

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:01:02

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:15:14
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: FLUOXETINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 18:39:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 18:39:40
Data point term sent to Coder	System	28 Aug 2020 18:39:02
User entered 'fluoxetine'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:38:53

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:01:02

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:15:20
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:38:53

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:01:02

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:15:25
User entered 'anxiety'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:38:53

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:01:02

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:15:30
User entered '20'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:38:53

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:01:02

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:15:32
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:38:53

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:01:02

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:15:35
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:38:53

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:01:02

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:15:55
User entered 'once daily (QD)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:38:53

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:01:02

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:15:56
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:38:53

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:01:02

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:16:01
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:38:53

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:01:02

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:16:02
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:38:53

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:01:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:16:06
User entered 'un UNK 2000'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:38:53

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:01:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:16:08
User entered '0'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:38:53

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:01:02

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:16:11
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:38:53

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:01:02

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:16:13
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:38:53

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:01:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:16:16
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:38:53

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:01:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 18:38:53

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:01:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 18:38:53

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:01:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Aug 2020 18:38:53

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:01:02

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:16:52
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Aug 2020 06:15:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Aug 2020 06:15:29
Data point term sent to Coder	System	28 Aug 2020 18:40:02
User entered 'corvedilol'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:39:23

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:01:02

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:16:55
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:39:23

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:01:02

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:17:00
User entered 'hypertension'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:39:23

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:01:02

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:17:03
User entered '25'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:39:23

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:01:02

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:17:05
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:39:23

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:01:02

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:17:07
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:39:23

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:01:02

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:17:10
User entered 'twice daily (BID)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:39:23

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:01:02

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:17:12
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:39:23

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:01:02

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:17:14
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:39:23

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:01:02

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:17:16
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:39:23

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:17:19
User entered 'un UNK 2017'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:39:23

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:01:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:17:21
User entered '0'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:39:23

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:01:02

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:17:26
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:39:23

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:01:02

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:17:28
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:39:23

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:01:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:17:34
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:39:23

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:01:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	28 Aug 2020 18:39:23

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:01:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 18:39:23

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:01:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Aug 2020 18:39:23

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:01:02

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:17:42
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 18:40:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 18:40:42
Data point term sent to Coder	System	28 Aug 2020 18:40:03
User entered 'atorvastatin'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:40:00

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:01:02

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:17:51
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:40:00

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:01:02

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:17:58
User entered 'hyperlipidemia'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:40:00

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:01:02

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:18:01
User entered '80'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:40:00

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:01:02

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:18:03
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:40:00

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:01:02

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:18:05
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:40:00

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:01:02

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:18:07
User entered 'once daily (QD)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:40:00

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:01:02

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:18:11
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:40:00

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:01:02

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:18:13
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:40:00

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:01:02

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:18:14
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:40:00

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:01:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:18:22
User entered 'un UNK 2018'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:40:00

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:01:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:18:24
User entered '0'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:40:00

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:01:02

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:18:27
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:40:00

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:01:02

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:18:31
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:40:00

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:01:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:18:37
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:40:00

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:01:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 18:40:00

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:01:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 18:40:00

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:01:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Aug 2020 18:40:00

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:01:02

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:18:43
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 21:04:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 21:04:41
Data point term sent to Coder	System	28 Aug 2020 18:41:04
User entered 'apixaban'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:40:45

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:01:02

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:18:53
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:40:45

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:01:02

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:18:55
User entered 'atril fibrillation'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:40:45

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:01:02

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:18:59
User entered '5'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:40:45

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:01:02

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:19:01
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:40:45

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:01:02

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:19:03
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:40:45

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:01:02

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:19:07
User entered 'once daily (QD)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:40:45

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:01:02

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:19:09
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:40:45

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:01:02

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:19:12
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:40:45

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:01:02

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:19:15
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:40:45

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:19:17
User entered 'un UNK 2017'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:40:45

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:01:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:19:19
User entered '0'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:40:45

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:01:02

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:19:22
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:40:45

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:01:02

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:19:24
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:40:45

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:01:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:19:47
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:40:45

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:01:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 18:40:45

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:01:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 18:40:45

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:01:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Aug 2020 18:40:45

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:01:02

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:20:09
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: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 18:42:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 18:42:50
Data point term sent to Coder	System	28 Aug 2020 18:42:06
User entered 'pantoprazole'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:41:20

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:01:02

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:20:11
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:41:20

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:01:02

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:25:08
User entered 'Gastroesophageal reflux disease'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:41:20

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:01:02

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:25:12
User entered '40'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:41:20

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:01:02

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:25:16
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:41:20

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:01:02

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:25:19
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:41:20

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:01:02

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:25:22
User entered 'once daily (QD)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:41:20

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:01:02

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:25:25
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:41:20

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:01:02

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:25:34
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:41:20

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:01:02

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:25:32
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:41:20

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:25:40
User entered 'un UNK 2018'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:41:20

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:01:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:25:43
User entered '0'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:41:20

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:01:02

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:25:45
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:41:20

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:01:02

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:25:55
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:41:20

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:01:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:26:03
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:41:20

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:01:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 18:41:20

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:01:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 18:41:20

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:01:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Aug 2020 18:41:20

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:01:02

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:28:15
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 18:42:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 18:42:49
Data point term sent to Coder	System	28 Aug 2020 18:42:06
User entered 'montelukast'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:41:46

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:01:02

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:28:28
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:41:46

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:01:02

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:28:37
User entered 'seasonal allergies'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:41:46

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:01:02

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:28:48
User entered '10'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:41:46

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:01:02

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:28:51
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:41:46

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:01:02

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:28:53
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:41:46

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:01:02

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:28:56
User entered 'once daily (QD)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:41:46

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:01:02

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:29:02
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:41:46

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:01:02

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:29:16
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:41:46

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:01:02

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:29:17
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:41:46

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:29:22
User entered 'un UNK 2018'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:41:46

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:01:02

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:29:30
User entered '0'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:41:46

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:01:02

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:29:36
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:41:46

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:01:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:29:38
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:41:46

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:01:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:29:52
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:41:46

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:01:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 18:41:46

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:01:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 18:41:46

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:01:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Aug 2020 18:41:46

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:01:02

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:31:45
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 18:43:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 18:43:51
Data point term sent to Coder	System	28 Aug 2020 18:43:07
User entered 'vitamin d'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:42:17

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:01:02

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:58:08
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:42:17

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:01:02

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:58:15
User entered 'health prophylaxis'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:42:17

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:01:02

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:58:19
User entered '1000'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:42:17

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:01:02

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:58:21
User entered 'Other (OTHER)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:42:17

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:01:02

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:58:24
User entered 'unit'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:42:17

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:01:02

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:58:28
User entered 'once daily (QD)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:42:17

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:01:02

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:58:29
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:42:17

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:01:02

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:58:31
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:42:17

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:01:02

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:58:34
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:42:17

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:58:39
User entered 'un May 2020'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:42:17

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:01:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:58:41
User entered '0'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:42:17

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:01:02

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:58:46
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:42:17

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:01:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:58:48
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:42:17

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:01:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:58:52
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:42:17

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:01:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 18:42:17

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:01:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 18:42:17

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:01:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Aug 2020 18:42:17

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:01:02

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:59:13
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: ZYRTEC [CETIRIZINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 18:43:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 18:43:52
Data point term sent to Coder User entered 'zyrtec'	System Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:43:10 28 Aug 2020 18:42:38

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:01:02

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:01:09
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:42:38

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:01:02

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:01:11
User entered 'seasonal allergies'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:42:38

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:01:02

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:01:14
User entered '10'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:42:38

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:01:02

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:01:16
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:42:38

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:01:02

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:01:18
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:42:38

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:01:02

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:01:20
User entered 'once daily (QD)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:42:38

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:01:02

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:01:22
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:42:38

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:01:02

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:01:25
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:42:38

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:01:02

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:01:28
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:42:38

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:01:30
User entered 'un UNK 2017'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:42:38

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:01:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:01:31
User entered '0'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:42:38

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:01:02

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:01:43
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:42:38

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:01:02

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:01:46
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:42:38

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:01:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:01:48
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:42:38

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:01:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 18:42:38

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:01:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 18:42:38

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:01:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Aug 2020 18:42:38

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:01:02

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:01:56
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) (b) (4)	28 Aug 2020 18:43:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 18:43:50
Data point term sent to Coder User entered 'aspirin'	System Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:43:11 28 Aug 2020 18:43:00

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:01:02

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:02:02
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:43:00

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:01:02

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:02:12
User entered 'cardiac prophylaxis'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:43:00

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:01:02

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:02:15
User entered '81'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:43:00

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:01:02

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:02:18
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:43:00

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:01:02

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:02:20
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:43:00

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:01:02

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:02:24
User entered 'once daily (QD)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:43:00

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:01:02

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:02:25
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:43:00

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:01:02

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:02:27
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:43:00

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:01:02

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:02:29
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:43:00

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:02:31
User entered 'un UNK 2017'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:43:00

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:01:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:02:33
User entered '0'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:43:00

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:01:02

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:02:39
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:43:00

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:01:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:02:41
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:43:00

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:01:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:02:44
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 18:43:00

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:01:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 18:43:00

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:01:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 18:43:00

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:01:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Aug 2020 18:43:00

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:01:02

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:48
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:02:52
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: POTASSIUM-SPARING AGENTS, ATC: ALDOSTERONE ANTAGONISTS, PRODUCT: SPIRONOLACTONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 20:54:43
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 Sep 2020 20:54:43
Data point term sent to Coder	System	10 Sep 2020 20:53:51
User entered 'SPIRONOLACTONE'	Karol Moore (b) (4) (b) (4)	10 Sep 2020 20:53:04

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:01:02

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:48
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:02:56
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	10 Sep 2020 20:53:04

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:01:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:48
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:02:59
User entered 'HYPERTENSION'	Karol Moore (b) (4) (b) (4)	10 Sep 2020 20:53:04

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:01:02

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:48
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:03:02
User entered '25'	Karol Moore (b) (4) (b) (4)	10 Sep 2020 20:53:04

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:01:02

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:48
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:03:03
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	10 Sep 2020 20:53:04

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:01:02

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:48
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:03:05
User entered empty.	Karol Moore (b) (4) (b) (4)	10 Sep 2020 20:53:04

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:01:02

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:48
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:03:07
User entered 'once daily (QD)'	Karol Moore (b) (4) (b) (4)	10 Sep 2020 20:53:04

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:01:02

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:48
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:03:09
User entered empty.	Karol Moore (b) (4) (b) (4)	10 Sep 2020 20:53:04

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:01:02

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:48
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:03:15
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	10 Sep 2020 20:53:04

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:01:02

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:48
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:03:21
User entered empty.	Karol Moore (b) (4) (b) (4)	10 Sep 2020 20:53:04

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:48
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:03:26
User entered 'UN UNK 2017'	Karol Moore (b) (4) (b) (4)	10 Sep 2020 20:53:04

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:01:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:48
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:03:28
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Sep 2020 20:53:04

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:01:02

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:48
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:03:29
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	10 Sep 2020 20:53:04

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:01:02

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:48
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:37:21
User closed query 'Source states 07AUG2020. Please review and reconcile ' (Site from CRA).	(b) (4), (b) (6)	26 Apr 2021 16:37:19
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
Query 'Source states 07AUG2020. Please review and reconcile ' answered with 'SOURCE SAYS 27AUG2020' (Site from CRA).	Karol Moore (b) (4)	23 Dec 2020 15:06:29
User entered '27 Aug 2020' reason for change: Data Entry Error	Karol Moore (b) (4)	23 Dec 2020 15:06:23
User opened query 'Source states 07AUG2020. Please review and reconcile ' (Site from CRA).	(b) (4), (b) (6)	22 Dec 2020 18:04:23
User entered '17 Aug 2020'	Karol Moore (b) (4)	10 Sep 2020 20:53:04

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:01:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:48
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:04:29
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	10 Sep 2020 20:53:04

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:01:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:48
User entered '1'	System	10 Sep 2020 20:53:04

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:01:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:48
User entered '1'	System	10 Sep 2020 20:53:04

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:01:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:48
User entered '804 (804)'	System	10 Sep 2020 20:53:04

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:01:02

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:05:04
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, EXCL. THIAZIDES, ATC: SULFONAMIDES, PLAIN, PRODUCT: CHLORTALIDONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 05:01:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 05:01:46
Data point term sent to Coder	System	10 Sep 2020 20:53:52
User entered 'CHLORPHALIDONE'	Karol Moore (b) (4) (b) (4)	10 Sep 2020 20:53:32

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:01:02

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:05:06
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	10 Sep 2020 20:53:32

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:01:02

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:05:10
User entered 'HYPERTENSION'	Karol Moore (b) (4) (b) (4)	10 Sep 2020 20:53:32

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:01:02

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:05:14
User entered '25'	Karol Moore (b) (4) (b) (4)	10 Sep 2020 20:53:32

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:01:02

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:05:15
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	10 Sep 2020 20:53:32

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:01:02

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:05:17
User entered empty.	Karol Moore (b) (4) (b) (4)	10 Sep 2020 20:53:32

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:01:02

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:05:20
User entered 'once daily (QD)'	Karol Moore (b) (4) (b) (4)	10 Sep 2020 20:53:32

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:01:02

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:05:22
User entered empty.	Karol Moore (b) (4) (b) (4)	10 Sep 2020 20:53:32

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:01:02

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:05:23
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	10 Sep 2020 20:53:32

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:01:02

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:05:25
User entered empty.	Karol Moore (b) (4) (b) (4)	10 Sep 2020 20:53:32

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:01:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:05:28
User entered '28 Aug 2020'	Karol Moore (b) (4) (b) (4)	10 Sep 2020 20:53:32

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:01:02

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:05:29
User entered '0'	Karol Moore (b) (4) (b) (4)	10 Sep 2020 20:53:32

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:01:02

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:05:34
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	10 Sep 2020 20:53:32

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:01:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:05:35
User entered empty.	Karol Moore (b) (4) (b) (4)	10 Sep 2020 20:53:32

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:01:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:06:02
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	10 Sep 2020 20:53:32

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:01:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 20:53:32

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:01:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 20:53:32

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:01:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 20:53:32

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:01:02

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:51
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:06:08
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) (b) (4)	21 Sep 2020 22:07:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 22:07:50
Data point term sent to Coder	System	21 Sep 2020 22:06:34
User entered 'ACETAMINOPHEN'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:05:43

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:01:02

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:51
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:06:11
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:05:43

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:01:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:51
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:06:17
User entered 'EXACERBATION OF LEFT RADICULOPATHY'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:05:43

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:01:02

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:51
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:06:19
User entered '500'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:05:43

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:01:02

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:51
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:06:23
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:05:43

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:01:02

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:51
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:06:25
User entered empty.	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:05:43

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:01:02

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:51
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:06:29
User entered 'once (ONCE)'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:05:43

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:01:02

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:51
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:06:31
User entered empty.	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:05:43

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:01:02

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:51
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:06:33
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:05:43

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:01:02

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:51
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:06:35
User entered empty.	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:05:43

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:51
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:06:38
User entered '12 Sep 2020'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:05:43

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:01:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:51
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:06:40
User entered '0'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:05:43

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:01:02

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:51
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:06:43
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:05:43

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:01:02

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:51
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:06:48
User entered '12 Sep 2020'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:05:43

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:01:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:51
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:06:49
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:05:43

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:01:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:51
User entered empty.	System	21 Sep 2020 22:05:43

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:01:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:51
User entered empty.	System	21 Sep 2020 22:05:43

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:01:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:51
User entered empty.	System	21 Sep 2020 22:05:43

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:01:02

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:06:57
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 05:41:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 05:41:48
Data point term sent to Coder	System	21 Sep 2020 22:06:34
User entered 'NAPROXEN'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:06:25

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:01:02

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:06:59
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:06:25

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:01:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:07:12
User entered 'EXACERABATION OF LEFT CERVIAL RADICULOPATHY'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:06:25

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:01:02

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:07:14
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 18:40:02
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'Updated. Thanks. ' (Site from DM).	Heather Barker (b) (4) (b) (4)	22 Oct 2020 23:16:51
User entered '220' reason for change: Data Entry Error	Heather Barker (b) (4) (b) (4)	22 Oct 2020 23:16:40
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 10:48:25
User entered '600'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:06:25

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:01:02

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:07:16
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:06:25

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:01:02

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:07:19
User entered empty.	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:06:25

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:01:02

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:07:26
User entered 'once (ONCE)'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:06:25

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:01:02

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:07:28
User entered empty.	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:06:25

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:01:02

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:07:30
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:06:25

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:01:02

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:07:32
User entered empty.	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:06:25

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:07:37
User entered '12 Sep 2020'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:06:25

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:01:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:07:40
User entered '0'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:06:25

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:01:02

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:07:44
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:06:25

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:01:02

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:07:46
User entered '12 Sep 2020'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:06:25

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:01:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:55
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:07:56
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:06:25

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:01:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:55
User entered empty.	System	21 Sep 2020 22:06:25

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:01:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:55
User entered empty.	System	21 Sep 2020 22:06:25

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:01:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:55
User entered empty.	System	21 Sep 2020 22:06:25

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:01:02

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:58
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:08:06
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 12:06:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 12:06:44
Data point term sent to Coder	System	21 Sep 2020 22:07:35
User entered 'IBUPROFEN'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:07:07

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:01:02

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:58
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:08:09
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:07:07

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:01:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:58
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:08:12
User entered 'EXACERBATION OF LEFT CERVIAL RADICULOPATHY'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:07:07

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:01:02

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:58
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:08:14
User entered '600'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:07:07

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:01:02

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:58
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:08:16
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:07:07

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:01:02

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:58
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:08:17
User entered empty.	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:07:07

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:01:02

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:58
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:08:21
User entered 'as needed (PRN)'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:07:07

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:01:02

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:58
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:08:23
User entered empty.	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:07:07

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:01:02

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:58
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:08:25
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:07:07

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:01:02

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:58
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:08:26
User entered empty.	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:07:07

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:58
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:08:28
User entered '12 Sep 2020'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:07:07

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:01:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:58
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:08:30
User entered '0'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:07:07

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:01:02

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:58
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:08:32
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:07:07

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:01:02

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:58
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:08:33
User entered '13 Sep 2020'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:07:07

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:01:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:58
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:08:35
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:07:07

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:01:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:58
User entered empty.	System	21 Sep 2020 22:07:07

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:01:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:58
User entered empty.	System	21 Sep 2020 22:07:07

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:01:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:42:58
User entered empty.	System	21 Sep 2020 22:07:07

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:01:02

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:08:40
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: OXYCODONE HYDROCHLORIDE;PARACETAMOL, PRODUCTSYNONYM: PERCOCET [OXYCODONE HYDROCHLORIDE;PARACETAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 05:49:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 05:49:56
Data point term sent to Coder	System	21 Sep 2020 22:08:37
User entered 'PERCOCET'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:07:56

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:01:02

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:08:43
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:07:56

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:01:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:08:48
User entered 'EXACERBATION OF LEFT CERVICAL RADICULOPATHY'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:07:56

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:01:02

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:08:50
User entered '5/325'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:07:56

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:01:02

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:08:52
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:07:56

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:01:02

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:08:55
User entered empty.	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:07:56

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:01:02

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:08:58
User entered 'as needed (PRN)'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:07:56

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:01:02

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:09:00
User entered empty.	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:07:56

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:01:02

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:09:02
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:07:56

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:01:02

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:09:04
User entered empty.	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:07:56

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:09:36
User entered '14 Sep 2020'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:07:56

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:01:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:09:38
User entered '0'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:07:56

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:01:02

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:09:48
User entered 'No (N)' reason for change: Data Entry Error	Heather Barker (b) (4) (b) (4)	22 Oct 2020 23:21:48
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:07:56

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:01:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:09:50
User entered '18 Sep 2020' reason for change: Data Entry Error	Heather Barker (b) (4)	22 Oct 2020 23:21:48
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:07:56

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:01:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:09:57
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:07:56

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:01:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:02
User entered empty.	System	21 Sep 2020 22:07:56

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:01:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:02
User entered empty.	System	21 Sep 2020 22:07:56

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:01:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:02
User entered empty.	System	21 Sep 2020 22:07:56

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:01:02

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:10:34
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ANDROGENS, ATC: 3-OXOANDROSTEN (4) DERIVATIVES, PRODUCT: TESTOSTERONE, PRODUCTSYNONYM: ANDROGEL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 04:58:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 04:58:55
Data point term sent to Coder	System	21 Sep 2020 22:09:37
User entered 'ANDROGEL TESTOSTERONE GEL 1.62%'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:08:49

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:01:02

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:10:38
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:08:49

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:01:02

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:10:40
User entered 'LOW TESTOSTERONE LEVELS'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:08:49

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:01:02

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:10:43
User entered '2'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:08:49

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:01:02

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:10:44
User entered 'Other (OTHER)'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:08:49

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:01:02

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:10:46
User entered 'PUMPS'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:08:49

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:01:02

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:10:52
User entered 'once daily (QD)'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:08:49

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:01:02

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:10:55
User entered empty.	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:08:49

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:01:02

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:10:57
User entered 'Topical (TOPICAL)'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:08:49

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:01:02

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:10:59
User entered empty.	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:08:49

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:11:01
User entered '04 Jun 2020'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:08:49

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:01:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:11:03
User entered '0'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:08:49

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:01:02

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:11:06
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:08:49

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:01:02

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:11:10
User entered empty.	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:08:49

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:01:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:11:18
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	21 Sep 2020 22:08:49

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:01:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 22:08:49

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:01:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 22:08:49

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:01:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Sep 2020 22:08:49

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:01:02

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:11:27
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 12:58:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 12:58:19
Data point term sent to Coder	System	06 Oct 2020 18:33:17
User entered 'cyclobenzaprine'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:33:00

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:01:02

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:11:30
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:33:00

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:01:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:11:34
User entered 'exacerbation of left cervical radiculopathy'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:33:00

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:01:02

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:11:36
User entered '10'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:33:00

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:01:02

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:11:38
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:33:00

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:01:02

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:11:41
User entered empty.	Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:33:00

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:01:02

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:11:46
User entered 'other (OTHER)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:33:00

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:01:02

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:11:48
User entered 'highly'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:33:00

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:01:02

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:11:57
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:33:00

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:01:02

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:11:59
User entered empty.	Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:33:00

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:12:04
User entered '30 Sep 2020'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:33:00

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:01:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:12:05
User entered '0'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:33:00

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:01:02

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:12:07
User entered 'No (N)' reason for change: Data Entry Error	Heather Barker (b) (4) (b) (4)	22 Oct 2020 23:21:13
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:33:00

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:01:02

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:12:10
User entered '09 Oct 2020' reason for change: Data Entry Error	Heather Barker (b) (4)	22 Oct 2020 23:21:13
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:33:00

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:01:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:12:12
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 18:33:00

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:01:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:06
User entered empty.	System	06 Oct 2020 18:33:00

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:01:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:06
User entered empty.	System	06 Oct 2020 18:33:00

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:01:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:06
User entered empty.	System	06 Oct 2020 18:33:00

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:01:02

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:09
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:12:20
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 16:54:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 16:54:46
Data point term sent to Coder	System	13 Nov 2020 16:53:57
User entered 'SEASONAL INFLUENZA VACCINE'	(b) (4), (b) (6)	13 Nov 2020 16:53:39

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:01:02

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:09
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:12:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Nov 2020 16:53:39

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:01:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:09
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:12:27
User entered 'SEASONAL INFLUENZA PROPHYLAXIS'	(b) (4), (b) (6)	13 Nov 2020 16:53:39

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:01:02

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:09
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:12:30
User entered '0.5'	(b) (4), (b) (6)	13 Nov 2020 16:53:39

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:01:02

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:09
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:12:32
User entered 'mL (mL)'	(b) (4), (b) (6)	13 Nov 2020 16:53:39

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:01:02

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:09
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:12:36
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 16:53:39

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:01:02

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:09
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:12:39
User entered 'once (ONCE)'	(b) (4), (b) (6)	13 Nov 2020 16:53:39

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:01:02

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:09
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:12:41
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 16:53:39

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:01:02

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:09
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User closed query 'Source states PO. Please review and reconcile.' (Site from CRA).	(b) (4), (b) (6)	28 Apr 2021 14:13:03
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
Query 'Source states PO. Please review and reconcile.' answered with 'UPDATED SOURCE' (Site from CRA).	(b) (4) Karol Moore (b) (4)	23 Dec 2020 15:03:33
User opened query 'Source states PO. Please review and reconcile.' (Site from CRA).	(b) (4), (b) (6)	22 Dec 2020 18:13:12
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	13 Nov 2020 16:53:39

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:01:02

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:09
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:13:16
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 16:53:39

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:09
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:13:19
User entered '06 Nov 2020'	(b) (4), (b) (6)	13 Nov 2020 16:53:39

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:01:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:09
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:13:23
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 16:53:39

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:01:02

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:09
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:13:25
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 16:53:39

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:01:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:09
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:13:41
User entered '06 Nov 2020'	(b) (4), (b) (6)	13 Nov 2020 16:53:39

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:01:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:09
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:13:45
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 16:53:39

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:01:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:09
User entered empty.	System	13 Nov 2020 16:53:39

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:01:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:09
User entered empty.	System	13 Nov 2020 16:53:39

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:01:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:09
User entered empty.	System	13 Nov 2020 16:53:39

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:01:02

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:13
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:15:53
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Dec 2020 15:11:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Dec 2020 15:11:59
Data point term sent to Coder	System	01 Dec 2020 15:10:46
User entered 'naproxen'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:10:20

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:01:02

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:13
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:16:23
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:10:20

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:01:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:13
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:17:22
User entered 'pneumonia'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:10:20

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:01:02

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:13
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:17:29
User entered '200'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:10:20

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:01:02

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:13
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:20:47
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:10:20

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:01:02

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:13
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:20:56
User entered empty.	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:10:20

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:01:02

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:13
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:20:58
User entered 'as needed (PRN)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:10:20

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:01:02

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:13
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:21:01
User entered empty.	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:10:20

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:01:02

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:13
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:21:03
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:10:20

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:01:02

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:13
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:21:07
User entered empty.	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:10:20

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:01:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:13
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:21:12
User entered '22 Nov 2020'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:10:20

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:01:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:13
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:21:15
User entered '0'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:10:20

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:01:02

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:13
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:21:19
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Dec 2020 22:57:01
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:10:20

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:01:02

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:13
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User closed query 'Source states 27NOV2020. Please review and reconcile. ' (Site from CRA).	(b) (4)	10 Mar 2021 20:54:29
Query 'Source states 27NOV2020. Please review and reconcile. ' answered with 'UPDATED PER SOURCE' (Site from CRA).	(b) (4), (b) (6)	23 Dec 2020 15:04:45
User entered '27 Nov 2020' reason for change: Data Entry Error	Karol Moore (b) (4)	23 Dec 2020 15:04:32
User opened query 'Source states 27NOV2020. Please review and reconcile. ' (Site from CRA).	(b) (4)	22 Dec 2020 18:22:55
User entered '30 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Dec 2020 22:57:01
User entered empty.	Karol Moore (b) (4)	01 Dec 2020 15:10:20
	(b) (4)	

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:01:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:13
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:22:57
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:10:20

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:01:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:13
User entered empty.	System	01 Dec 2020 15:10:20

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:01:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:13
User entered empty.	System	01 Dec 2020 15:10:20

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:01:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:13
User entered empty.	System	01 Dec 2020 15:10:20

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:01:02

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:16
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:23:12
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: THROAT PREPARATIONS, ATC: THROAT PREPARATIONS, ATC: OTHER THROAT PREPARATIONS, PRODUCT: PECTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 01:48:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 01:48:49
Data point term sent to Coder	System	01 Dec 2020 15:11:51
User entered 'luden's cough drop (pectin 2.8mg)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:11:29

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:01:02

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:16
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:23:27
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:11:29

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:01:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:16
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:23:30
User entered 'pneumonia'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:11:29

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:01:02

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:16
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:23:33
User entered 'I'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:11:29

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:01:02

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:16
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:23:35
User entered 'Other (OTHER)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:11:29

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:01:02

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:16
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:23:38
User entered 'lozenge'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:11:29

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:01:02

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:16
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:23:42
User entered 'as needed (PRN)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:11:29

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:01:02

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:16
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:23:43
User entered empty.	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:11:29

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:01:02

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:16
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:23:52
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:11:29

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:01:02

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:16
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:23:54
User entered empty.	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:11:29

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:16
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:23:57
User entered '22 Nov 2020'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:11:29

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:01:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:16
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:23:59
User entered '0'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:11:29

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:01:02

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:16
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:24:05
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Dec 2020 22:56:45
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:11:29

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:01:02

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:16
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:24:07
User entered '30 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Dec 2020 22:56:45
User entered empty.	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:11:29

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:01:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:16
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:24:09
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:11:29

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:01:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:16
User entered empty.	System	01 Dec 2020 15:11:29

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:01:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:16
User entered empty.	System	01 Dec 2020 15:11:29

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:01:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:16
User entered empty.	System	01 Dec 2020 15:11:29

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:01:02

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:20
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:24:16
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: THROAT PREPARATIONS, ATC: THROAT PREPARATIONS, ATC: ANTISEPTICS, PRODUCT: PHENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Dec 2020 00:08:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Dec 2020 00:08:46
Data point term sent to Coder	System	01 Dec 2020 15:12:52
User entered 'phenol 1.4%'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:12:51

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:01:02

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:20
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:24:18
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:12:51

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:01:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:20
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:24:21
User entered 'penumonia'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:12:51

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:01:02

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:20
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:25:32
User entered '2'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:12:51

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:01:02

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:20
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:25:35
User entered 'Other (OTHER)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:12:51

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:01:02

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:20
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:25:37
User entered 'sprays'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:12:51

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:01:02

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:20
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:25:44
User entered 'as needed (PRN)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:12:51

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:01:02

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:20
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:25:46
User entered empty.	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:12:51

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:01:02

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:20
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:25:52
User entered 'Other (OTHER)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:12:51

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:01:02

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:20
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:26:09
User entered 'intra-oral-pharyngeal'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:12:51

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:20
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:26:15
User entered '22 Nov 2020'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:12:51

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:01:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:20
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:26:17
User entered '0'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:12:51

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:01:02

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:20
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:26:19
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Dec 2020 22:57:37
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:12:51

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:01:02

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:20
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:26:21
User entered '30 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Dec 2020 22:57:37
User entered empty.	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:12:51

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:01:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:20
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:26:23
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:12:51

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:01:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:20
User entered empty.	System	01 Dec 2020 15:12:51

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:01:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:20
User entered empty.	System	01 Dec 2020 15:12:51

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:01:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:20
User entered empty.	System	01 Dec 2020 15:12:51

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:01:02

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:31:53
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) (b) (4)	11 Dec 2020 04:05:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 04:05:00
Data point term sent to Coder	System	01 Dec 2020 15:13:55
User entered 'Bilevel Positive Airway Pressure'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:13:40

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:01:02

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:32:18
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:13:40

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:01:02

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:32:27
User entered 'sleep apnea'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:13:40

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:01:02

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:32:30
User entered 'I'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:13:40

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:01:02

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:32:33
User entered 'Other (OTHER)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:13:40

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:01:02

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:32:37
User entered 'unit'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:13:40

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:01:02

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:32:41
User entered 'once daily (QD)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:13:40

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:01:02

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:32:44
User entered empty.	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:13:40

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:01:02

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:32:47
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:13:40

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:01:02

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:32:49
User entered empty.	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:13:40

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:32:52
User entered 'un UNK 2017'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:13:40

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:01:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:32:54
User entered '0'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:13:40

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:01:02

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:32:59
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:13:40

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:01:02

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:33:02
User entered empty.	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:13:40

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:01:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:33:04
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:13:40

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:01:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Dec 2020 15:13:40

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:01:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Dec 2020 15:13:40

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:01:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Dec 2020 15:13:40

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:01:02

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:33:18
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMOXICILLIN;CLAVULANIC ACID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Dec 2020 17:32:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Dec 2020 17:32:51
Data point term sent to Coder	System	01 Dec 2020 15:17:00
User entered 'amoxicillin/clavulanate'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:16:55

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:01:02

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:33:21
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:16:55

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:01:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:33:27
User entered 'pneumonia'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:16:55

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:01:02

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:33:30
User entered '875/125'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:16:55

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:01:02

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:33:32
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:16:55

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:01:02

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:33:35
User entered empty.	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:16:55

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:01:02

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:33:39
User entered 'twice daily (BID)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:16:55

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:01:02

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:33:42
User entered empty.	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:16:55

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:01:02

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:33:44
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:16:55

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:01:02

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:33:47
User entered empty.	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:16:55

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:33:50
User entered '25 Nov 2020'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:16:55

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:01:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:33:53
User entered '0'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:16:55

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:01:02

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:33:56
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Dec 2020 22:57:59
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:16:55

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:01:02

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:33:59
User entered '30 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Dec 2020 22:57:59
User entered empty.	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:16:55

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:01:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:24
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 18:34:03
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:16:55

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:01:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:24
User entered '2'	System	01 Dec 2020 15:16:55

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:01:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:24
User entered '1'	System	01 Dec 2020 15:16:55

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:01:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:24
User entered '804 (804)'	System	01 Dec 2020 15:16:55

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:01:02

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN HYDROCHLORIDE, PRODUCTSYNONYM: METFORMIN HCL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Jan 2021 16:45:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 16:45:29
Data point term sent to Coder	System	05 Jan 2021 16:44:21
User entered 'Metformin HCL'	(b) (4), (b) (6)	05 Jan 2021 16:43:48

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:01:02

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:43:48

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:01:02

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Pre-Diabetes'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:43:48

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:01:02

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '500'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:43:48

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:01:02

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:43:48

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:01:02

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:43:48

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:01:02

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:43:48

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:01:02

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:43:48

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:01:02

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:43:48

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:01:02

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:43:48

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '29 Dec 2020'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:43:48

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:01:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:43:48

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:01:02

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:43:48

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:01:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:43:48

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:01:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:43:48

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:01:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Jan 2021 16:43:48

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:01:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Jan 2021 16:43:48

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:01:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Jan 2021 16:43:48

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:01:02

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:29
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: METHYLPREDNISOLONE SODIUM SUCCINATE, PRODUCTSYNONYM: SOLUMEDROL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Jan 2021 17:22:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Jan 2021 17:22:54
Data point term sent to Coder	System	13 Jan 2021 16:21:23
User entered 'solumedrol'	Karol Moore (b) (4)	13 Jan 2021 16:20:42
	(b) (4)	

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:01:02

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:29
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'No (N)'	(b) (4)	
	Karol Moore (b) (4)	13 Jan 2021 16:20:42
	(b) (4)	

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:01:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:29
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'PNEUMONIA'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Jan 2021 16:20:42

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:01:02

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:29
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'UNK'	(b) (4)	
	Karol Moore (b) (4)	13 Jan 2021 16:20:42
	(b) (4)	

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:01:02

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:29
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'mg (mg)'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Jan 2021 16:20:42

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:01:02

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:29
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered empty.	(b) (4)	
	Karol Moore (b) (4)	13 Jan 2021 16:20:42
	(b) (4)	

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:01:02

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:29
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'once (ONCE)'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Jan 2021 16:20:42

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:01:02

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:29
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered empty.	(b) (4)	
	Karol Moore (b) (4)	13 Jan 2021 16:20:42
	(b) (4)	

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:01:02

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:29
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Jan 2021 16:20:42

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:01:02

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:29
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered empty.	(b) (4)	13 Jan 2021 16:20:42
	Karol Moore (b) (4)	
	(b) (4)	

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:29
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '28 Nov 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Jan 2021 16:20:42

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:01:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:29
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Jan 2021 16:20:42

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:01:02

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:29
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'No (N)'	(b) (4)	
	Karol Moore (b) (4)	13 Jan 2021 16:20:42
	(b) (4)	

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:01:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:29
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '28 Nov 2020'	(b) (4)	
	Karol Moore (b) (4)	13 Jan 2021 16:20:42
	(b) (4)	

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:01:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:29
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'No (N)'	(b) (4)	
	Karol Moore (b) (4)	13 Jan 2021 16:20:42
	(b) (4)	

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:01:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:29
User entered empty.	System	13 Jan 2021 16:20:42

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:01:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:29
User entered empty.	System	13 Jan 2021 16:20:42

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:01:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:29
User entered empty.	System	13 Jan 2021 16:20:42

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:01:02

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:34
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Jan 2021 14:42:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Jan 2021 14:42:54
Data point term sent to Coder	System	13 Jan 2021 16:23:23
User entered 'BENADRYL'	Karol Moore (b) (4)	13 Jan 2021 16:23:05

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:01:02

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:34
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'No (N)'	(b) (4)	
	Karol Moore (b) (4)	13 Jan 2021 16:23:05
	(b) (4)	

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:01:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:34
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'PNEUMONIA'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Jan 2021 16:23:05

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:01:02

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:34
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'UNK'	(b) (4)	
	Karol Moore (b) (4)	13 Jan 2021 16:23:05
	(b) (4)	

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:01:02

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:34
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'mg (mg)'	(b) (4)	
	Karol Moore (b) (4)	13 Jan 2021 16:23:05
	(b) (4)	

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:01:02

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:34
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered empty.	(b) (4)	
	Karol Moore (b) (4)	13 Jan 2021 16:23:05
	(b) (4)	

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:01:02

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:34
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'once (ONCE)'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Jan 2021 16:23:05

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:01:02

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:34
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered empty.	(b) (4)	
	Karol Moore (b) (4)	13 Jan 2021 16:23:05
	(b) (4)	

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:01:02

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:34
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Jan 2021 16:23:05

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:01:02

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:34
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered empty.	(b) (4)	
	Karol Moore (b) (4)	13 Jan 2021 16:23:05
	(b) (4)	

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:34
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '28 Nov 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Jan 2021 16:23:05

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:01:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:34
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '0'	(b) (4)	
	Karol Moore (b) (4)	13 Jan 2021 16:23:05
	(b) (4)	

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:01:02

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:34
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'No (N)'	(b) (4)	
	Karol Moore (b) (4)	13 Jan 2021 16:23:05
	(b) (4)	

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:01:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:34
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '28 Nov 2020'	(b) (4)	
	Karol Moore (b) (4)	13 Jan 2021 16:23:05
	(b) (4)	

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:01:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:34
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'No (N)'	(b) (4)	
	Karol Moore (b) (4)	13 Jan 2021 16:23:05
	(b) (4)	

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:01:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:34
User entered empty.	System	13 Jan 2021 16:23:05

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:01:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:34
User entered empty.	System	13 Jan 2021 16:23:05

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:01:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:34
User entered empty.	System	13 Jan 2021 16:23:05

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:01:02

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:37
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Jan 2021 16:25:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Jan 2021 16:25:01
Data point term sent to Coder	System	13 Jan 2021 16:24:24
User entered 'Ceftriaxone'	Karol Moore (b) (4)	13 Jan 2021 16:24:17

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:01:02

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:37
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'No (N)'	(b) (4)	
	Karol Moore (b) (4)	13 Jan 2021 16:24:17
	(b) (4)	

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:01:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:37
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'PNEUMONIA'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Jan 2021 16:24:17

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:01:02

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:37
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'UNK'	(b) (4)	
	Karol Moore (b) (4)	13 Jan 2021 16:24:17
	(b) (4)	

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:01:02

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:37
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'mg (mg)'	(b) (4)	
	Karol Moore (b) (4)	13 Jan 2021 16:24:17
	(b) (4)	

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:01:02

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:37
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered empty.	(b) (4)	
	Karol Moore (b) (4)	13 Jan 2021 16:24:17
	(b) (4)	

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:01:02

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:37
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'unknown (UNKNOWN)'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Jan 2021 16:24:17

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:01:02

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:37
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered empty.	(b) (4)	
	Karol Moore (b) (4)	13 Jan 2021 16:24:17
	(b) (4)	

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:01:02

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:37
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Jan 2021 16:24:17

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:01:02

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:37
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered empty.	(b) (4)	13 Jan 2021 16:24:17
	Karol Moore (b) (4)	
	(b) (4)	

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:37
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '28 Nov 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Jan 2021 16:24:17

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:01:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:37
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '0'	(b) (4)	
	Karol Moore (b) (4)	13 Jan 2021 16:24:17
	(b) (4)	

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:01:02

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:37
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'No (N)'	(b) (4)	
	Karol Moore (b) (4)	13 Jan 2021 16:24:17
	(b) (4)	

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:01:02

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:37
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '01 Dec 2020'	(b) (4)	
	Karol Moore (b) (4)	13 Jan 2021 16:24:17
	(b) (4)	

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:01:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:37
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'No (N)'	(b) (4)	
	Karol Moore (b) (4)	13 Jan 2021 16:24:17
	(b) (4)	

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:01:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:37
User entered empty.	System	13 Jan 2021 16:24:17

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:01:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:37
User entered empty.	System	13 Jan 2021 16:24:17

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:01:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:37
User entered empty.	System	13 Jan 2021 16:24:17

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:01:02

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:44
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	13 Jan 2021 16:26:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	13 Jan 2021 16:26:01
Data point term sent to Coder	System	13 Jan 2021 16:25:25
User entered 'azithromycin'	Karol Moore (b) (4)	13 Jan 2021 16:25:23

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:01:02

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:44
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'No (N)'	(b) (4)	
	Karol Moore (b) (4)	13 Jan 2021 16:25:23
	(b) (4)	

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:01:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:44
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'PNEUMONIA'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Jan 2021 16:25:23

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:01:02

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:44
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'UNK'	(b) (4)	
	Karol Moore (b) (4)	13 Jan 2021 16:25:23
	(b) (4)	

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:01:02

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:44
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'mg (mg)'	(b) (4)	
	Karol Moore (b) (4)	13 Jan 2021 16:25:23
	(b) (4)	

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:01:02

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:44
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered empty.	(b) (4)	
	Karol Moore (b) (4)	13 Jan 2021 16:25:23
	(b) (4)	

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:01:02

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:44
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'unknown (UNKNOWN)'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Jan 2021 16:25:23

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:01:02

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:44
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered empty.	(b) (4)	
	Karol Moore (b) (4)	13 Jan 2021 16:25:23
	(b) (4)	

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:01:02

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:44
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Jan 2021 16:25:23

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:01:02

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:44
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered empty.	(b) (4)	
	Karol Moore (b) (4)	13 Jan 2021 16:25:23
	(b) (4)	

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:44
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '28 Nov 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Jan 2021 16:25:23

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:01:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:44
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '0'	(b) (4)	
	Karol Moore (b) (4)	13 Jan 2021 16:25:23
	(b) (4)	

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:01:02

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:44
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'No (N)'	(b) (4)	
	Karol Moore (b) (4)	13 Jan 2021 16:25:23
	(b) (4)	

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:01:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:44
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '01 Dec 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Jan 2021 16:25:23

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:01:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:44
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'No (N)'	(b) (4)	
	Karol Moore (b) (4)	13 Jan 2021 16:25:23
	(b) (4)	

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:01:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:44
User entered empty.	System	13 Jan 2021 16:25:23

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:01:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:44
User entered empty.	System	13 Jan 2021 16:25:23

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:01:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:44
User entered empty.	System	13 Jan 2021 16:25:23

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:01:02

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:49
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: MEDICAL GASES, PRODUCT: OXYGEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	15 Jan 2021 09:52:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Jan 2021 09:52:49
Data point term sent to Coder	System	13 Jan 2021 16:28:27
User entered 'OXYGEN'	Karol Moore (b) (4) (b) (4)	13 Jan 2021 16:27:31

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:01:02

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:49
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'No (N)'	(b) (4)	
	Karol Moore (b) (4)	13 Jan 2021 16:27:31
	(b) (4)	

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:01:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:49
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'PNEUMONIA'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Jan 2021 16:27:31

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:01:02

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:49
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '2'	(b) (4)	
	Karol Moore (b) (4)	13 Jan 2021 16:27:31
	(b) (4)	

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:01:02

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:49
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Other (OTHER)'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Jan 2021 16:27:31

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:01:02

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:49
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'LITERS'	(b) (4)	
	Karol Moore (b) (4)	13 Jan 2021 16:27:31
	(b) (4)	

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:01:02

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:49
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'other (OTHER)'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Jan 2021 16:27:31

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:01:02

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:49
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'CONTINUOUS'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Jan 2021 16:27:31

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:01:02

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:49
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Other (OTHER)'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Jan 2021 16:27:31

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:01:02

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:49
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'NASAL CANNULA'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Jan 2021 16:27:31

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:49
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '28 Nov 2020'	(b) (4)	
	Karol Moore (b) (4)	13 Jan 2021 16:27:31
	(b) (4)	

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:01:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:49
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Jan 2021 16:27:31

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:01:02

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:49
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'No (N)'	(b) (4)	
	Karol Moore (b) (4)	13 Jan 2021 16:27:31
	(b) (4)	

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:01:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:49
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '30 Nov 2020'	(b) (4)	
	Karol Moore (b) (4)	13 Jan 2021 16:27:31
	(b) (4)	

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:01:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:49
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'No (N)'	(b) (4)	
	Karol Moore (b) (4)	13 Jan 2021 16:27:31
	(b) (4)	

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:01:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:49
User entered empty.	System	13 Jan 2021 16:27:31

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:01:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:49
User entered empty.	System	13 Jan 2021 16:27:31

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:01:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:49
User entered empty.	System	13 Jan 2021 16:27:31

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:01:02

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	16 Apr 2021 16:28:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 16:28:57
Data point term sent to Coder	System	16 Apr 2021 13:21:54
User entered 'TRAMADOL'	(b) (4), (b) (6)	16 Apr 2021 13:21:09

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:01:02

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:21:09

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:01:02

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User entered 'SPINAL DISC HERNIATION'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:21:09

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:01:02

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User entered '50'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:21:09

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:01:02

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:21:09

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:01:02

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:21:09

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:01:02

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:21:09

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:01:02

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:21:09

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:01:02

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:21:09

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:01:02

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:21:09

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User entered '08 Apr 2021'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:21:09

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:01:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:21:09

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:01:02

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:21:09

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:01:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User entered '10 Apr 2021'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:21:09

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:01:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:21:09

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:01:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 13:21:09

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:01:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 13:21:09

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:01:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 13:21:09

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:01:02

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Apr 2021 16:20:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Apr 2021 16:20:45
Data point term sent to Coder	System	16 Apr 2021 13:22:55
User entered 'OXYCODONE'	(b) (4), (b) (6)	16 Apr 2021 13:22:01

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:01:02

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:22:01

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:01:02

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User entered 'SPINAL DISC HERNIATION'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:22:01

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:01:02

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User entered '325'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:22:01

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:01:02

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:22:01

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:01:02

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:22:01

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:01:02

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:22:01

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:01:02

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:22:01

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:01:02

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:22:01

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:01:02

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:22:01

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User entered '10 Apr 2021'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:22:01

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:01:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:22:01

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:01:02

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:22:01

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:01:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:22:01

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:01:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:22:01

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:01:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 13:22:01

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:01:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 13:22:01

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:01:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 13:22:01

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:01:02

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Apr 2021 16:26:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Apr 2021 16:26:45
Data point term sent to Coder	System	16 Apr 2021 13:22:55
User entered 'PREDNISONE'	(b) (4), (b) (6)	16 Apr 2021 13:22:45

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:01:02

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:22:45

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:01:02

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User entered 'SPINAL DISC HERNIATION'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:22:45

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:01:02

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User entered '25'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:22:45

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:01:02

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:22:45

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:01:02

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:22:45

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:01:02

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:22:45

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:01:02

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:22:45

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:01:02

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:22:45

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:01:02

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:22:45

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User entered '10 Apr 2021'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:22:45

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:01:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:22:45

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:01:02

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:22:45

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:01:02

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:22:45

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:01:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:13:08
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:40:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:22:45

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:01:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 13:22:45

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:01:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 13:22:45

US3312197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:01:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 13:22:45

US3312197

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:01:02

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:25:49
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Yes (Y)'	(b) (4)	13 Jan 2021 16:18:31
	Karol Moore (b) (4)	
	(b) (4)	

US3312197

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:01:02

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
	(b) (4)	
User entered '28 Nov 2020'	Karol Moore (b) (4)	13 Jan 2021 16:18:52
	(b) (4)	

US3312197

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:01:02

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
	(b) (4)	
User entered 'electrocardiogram'	Karol Moore (b) (4)	13 Jan 2021 16:18:52
	(b) (4)	

US3312197

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:01:02

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
	(b) (4)	
User entered 'Adverse Event (AE)'	Karol Moore (b) (4)	13 Jan 2021 16:18:52
	(b) (4)	

US3312197

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:01:02

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	13 Jan 2021 16:18:52
	(b) (4)	

US3312197

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:01:02

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:25
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '28 Nov 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Jan 2021 16:19:09

US3312197

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:01:02

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:25
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'CHEST X-RAY'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Jan 2021 16:19:09

US3312197

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:01:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:25
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered 'Adverse Event (AE)'	(b) (4) Karol Moore (b) (4) (b) (4)	13 Jan 2021 16:19:09

US3312197

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:01:02

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:25
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	13 Jan 2021 16:19:09

US3312197

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:01:02

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User entered '17 Sep 2020'	(b) (4) Heather Barker (b) (4) (b) (4)	22 Oct 2020 23:15:36

US3312197

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:01:02

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
User closed query "Per CDM: Primary reason for dosing discontinuation is recorded as 'Due to AE', However, no data is recorded on 'End of Study / Study Discontinuation' form. Kindly verify and consider to update all the necessary eCRFs required else clarify." (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 14:41:06
Query "Per CDM: Primary reason for dosing discontinuation is recorded as 'Due to AE', However, no data is recorded on 'End of Study / Study Discontinuation' form. Kindly verify and consider to update all the necessary eCRFs required else clarify.' answered with 'SUBJECT DID NOT RECEIVE DAY 29 DOSING (DOSING DISCONTINUATION UPDATED) BUT AGREES TO CONTINUE IN STUDY FOR SAFETY (EOS PAGE NOT COMPLETED)' (Site from DM).	Monica Atwood (b) (4) (b) (4)	07 Nov 2020 00:25:26
User opened query "Per CDM: Primary reason for dosing discontinuation is recorded as 'Due to AE', However, no data is recorded on 'End of Study / Study Discontinuation' form. Kindly verify and consider to update all the necessary eCRFs required else clarify." (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 13:15:55
User entered 'AE (specify) (ADVERSE EVENT)'	Heather Barker (b) (4) (b) (4)	22 Oct 2020 23:15:36

US3312197

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:01:02

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 11:50:59
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:15
Query 'Per CDM: Dosing discontinuation = AE#2, however Action taken with investigational product = None in the AE section of the eCRF. Kindly review and update as needed, else provide clarification.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Feb 2021 05:39:08
User opened query 'Per CDM: Dosing discontinuation = AE#2, however Action taken with investigational product = None in the AE section of the eCRF. Kindly review and update as needed, else provide clarification.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 21:16:29
User closed query 'Per CDM Re-query: thank you for the update however, per CCGs, please remove the extra details as AE#2 is only required. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 08:39:59
Query 'Per CDM Re-query: thank you for the update however, per CCGs, please remove the extra details as AE#2 is only required. ' answered with 'UPADTED' (Site from DM).	Karol Moore (b) (4) (b) (4)	23 Nov 2020 18:33:31
User entered 'AE#2' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	23 Nov 2020 18:33:26
User opened query 'Per CDM Re-query: thank you for the update however, per CCGs, please remove the extra details as AE#2 is only required. ' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 22:36:55
User closed query 'Per CDM: please record AE record number (i.e. AE #1, etc.) instead of details' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 22:36:55
Query 'Per CDM: please record AE record number (i.e. AE #1, etc.) instead of details' answered with 'UPDATED' (Site from DM).	Monica Atwood (b) (4) (b) (4)	20 Nov 2020 16:10:51
User entered 'AE#2-EXACERBATION OF LEFT CERVICAL RADICULOPATHY' reason for change: Data Entry Error	Monica Atwood (b) (4) (b) (4)	20 Nov 2020 16:08:53
User opened query 'Per CDM: please record AE record number (i.e. AE #1, etc.) instead of details' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 14:56:48

US3312197

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:01:02

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

Audit	User	Time (GMT)
User entered 'EXACERBATION OF LEFT CERVICAL RADICULOPATHY' reason for change: Data Entry Error	Heather Barker (b) (4)	22 Oct 2020 23:18:24
User entered 'Unstable left cervical radiculopathy'	Heather Barker (b) (4)	22 Oct 2020 23:15:36

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:23
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'USA-US300-2020-MRNA-1273-P301000015'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

Serious

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'Yes (Y)'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:28
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'No (N)'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:30
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'No (N)'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'Yes (Y)'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:36
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'No (N)'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:38
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'No (N)'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:42
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'No (N)'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:59
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'Carlos'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:06:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'Fierro'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:06:03
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered '16300 College Blvd'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:39:54
User closed query 'Site is located in Lenexa. Please review and reconcile ' (Site from CRA).	(b) (4), (b) (6)	26 Apr 2021 16:39:52
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
Query 'Site is located in Lenexa. Please review and reconcile ' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	17 Mar 2021 19:45:28
Un-reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 19:45:21
User entered 'Lenexa' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 19:45:21
User opened query 'Site is located in Lenexa. Please review and reconcile ' (Site from CRA).	(b) (4), (b) (6)	22 Dec 2020 17:10:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'Shawnee'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:06:16
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'KS'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:11:06
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered '66219'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:11:07
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 18:23:17
User entered 'US'	System	01 Dec 2020 13:42:35

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	17 Feb 2021 16:06:30
User entered '7'	System	02 Feb 2021 15:58:03
User entered '6'	System	12 Jan 2021 16:47:50
User entered '5'	System	28 Dec 2020 14:02:50
User entered '4'	System	22 Dec 2020 21:36:52
User entered '3'	System	18 Dec 2020 19:39:00
User entered '2'	System	09 Dec 2020 18:23:27
User entered '1'	System	01 Dec 2020 13:42:35

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:23
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'USA-US300-2020-MRNA-1273-P301000015'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

Serious

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'Yes (Y)'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:28
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'No (N)'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:30
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'No (N)'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'Yes (Y)'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:36
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'No (N)'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:38
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'No (N)'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:42
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'No (N)'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:59
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'Carlos'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:06:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'Fierro'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:06:03
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered '16300 College Blvd'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:39:54
User closed query 'Site is located in Lenexa. Please review and reconcile ' (Site from CRA).	(b) (4), (b) (6)	26 Apr 2021 16:39:52
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
Query 'Site is located in Lenexa. Please review and reconcile ' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	17 Mar 2021 19:45:28
Un-reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 19:45:21
User entered 'Lenexa' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 19:45:21
User opened query 'Site is located in Lenexa. Please review and reconcile ' (Site from CRA).	(b) (4), (b) (6)	22 Dec 2020 17:10:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'Shawnee'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:06:16
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'KS'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:11:06
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered '66219'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:11:07
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 18:23:17
User entered 'US'	System	01 Dec 2020 13:42:35

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	17 Feb 2021 16:06:30
User entered '7'	System	02 Feb 2021 15:58:03
User entered '6'	System	12 Jan 2021 16:47:50
User entered '5'	System	28 Dec 2020 14:02:50
User entered '4'	System	22 Dec 2020 21:36:52
User entered '3'	System	18 Dec 2020 19:39:00
User entered '2'	System	09 Dec 2020 18:23:27
User entered '1'	System	01 Dec 2020 13:42:35

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:01:02

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:40:07
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered '01/Dec/2020 08:42'	(b) (4) System	01 Dec 2020 13:42:35

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:01:02

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)	26 Apr 2021 16:40:09
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:23:17
User entered 'I'	(b) (4), (b) (6)	01 Dec 2020 13:42:35

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:23
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'USA-US300-2020-MRNA-1273-P301000015'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

Serious

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'Yes (Y)'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:28
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'No (N)'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:30
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'No (N)'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'Yes (Y)'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:36
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'No (N)'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:38
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'No (N)'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:42
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'No (N)'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:59
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'Carlos'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:06:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'Fierro'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:06:03
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered '16300 College Blvd'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:39:54
User closed query 'Site is located in Lenexa. Please review and reconcile ' (Site from CRA).	(b) (4), (b) (6)	26 Apr 2021 16:39:52
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
Query 'Site is located in Lenexa. Please review and reconcile ' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	17 Mar 2021 19:45:28
Un-reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 19:45:21
User entered 'Lenexa' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 19:45:21
User opened query 'Site is located in Lenexa. Please review and reconcile ' (Site from CRA).	(b) (4), (b) (6)	22 Dec 2020 17:10:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'Shawnee'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:06:16
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'KS'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:11:06
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered '66219'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:11:07
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 18:23:17
User entered 'US'	System	01 Dec 2020 13:42:35

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	17 Feb 2021 16:06:30
User entered '7'	System	02 Feb 2021 15:58:03
User entered '6'	System	12 Jan 2021 16:47:50
User entered '5'	System	28 Dec 2020 14:02:50
User entered '4'	System	22 Dec 2020 21:36:52
User entered '3'	System	18 Dec 2020 19:39:00
User entered '2'	System	09 Dec 2020 18:23:27
User entered '1'	System	01 Dec 2020 13:42:35

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:01:02

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:40:16
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered '09/Dec/2020 18:23'	(b) (4) System	09 Dec 2020 18:23:27

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:01:02

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)	26 Apr 2021 16:40:19
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 19:38:44
User entered 'I'	(b) (4), (b) (6)	09 Dec 2020 18:23:27

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:23
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'USA-US300-2020-MRNA-1273-P301000015'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

Serious

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'Yes (Y)'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:28
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'No (N)'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:30
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'No (N)'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'Yes (Y)'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:36
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'No (N)'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:38
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'No (N)'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:42
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'No (N)'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:59
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'Carlos'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:06:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'Fierro'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:06:03
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered '16300 College Blvd'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:39:54
User closed query 'Site is located in Lenexa. Please review and reconcile ' (Site from CRA).	(b) (4), (b) (6)	26 Apr 2021 16:39:52
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
Query 'Site is located in Lenexa. Please review and reconcile ' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	17 Mar 2021 19:45:28
Un-reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 19:45:21
User entered 'Lenexa' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 19:45:21
User opened query 'Site is located in Lenexa. Please review and reconcile ' (Site from CRA).	(b) (4), (b) (6)	22 Dec 2020 17:10:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'Shawnee'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:06:16
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'KS'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:11:06
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered '66219'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:11:07
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 18:23:17
User entered 'US'	System	01 Dec 2020 13:42:35

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	17 Feb 2021 16:06:30
User entered '7'	System	02 Feb 2021 15:58:03
User entered '6'	System	12 Jan 2021 16:47:50
User entered '5'	System	28 Dec 2020 14:02:50
User entered '4'	System	22 Dec 2020 21:36:52
User entered '3'	System	18 Dec 2020 19:39:00
User entered '2'	System	09 Dec 2020 18:23:27
User entered '1'	System	01 Dec 2020 13:42:35

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:01:02

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:40:25
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered '18/Dec/2020 14:38'	(b) (4) System	18 Dec 2020 19:39:00

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:01:02

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)	26 Apr 2021 16:40:27
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 19:39:05
User entered 'I'	(b) (4), (b) (6)	18 Dec 2020 19:39:00

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:23
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'USA-US300-2020-MRNA-1273-P301000015'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

Serious

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'Yes (Y)'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:28
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'No (N)'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:30
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'No (N)'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'Yes (Y)'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:36
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'No (N)'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:38
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'No (N)'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:42
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'No (N)'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:59
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'Carlos'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:06:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'Fierro'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:06:03
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered '16300 College Blvd'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:39:54
User closed query 'Site is located in Lenexa. Please review and reconcile ' (Site from CRA).	(b) (4), (b) (6)	26 Apr 2021 16:39:52
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
Query 'Site is located in Lenexa. Please review and reconcile ' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	17 Mar 2021 19:45:28
Un-reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 19:45:21
User entered 'Lenexa' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 19:45:21
User opened query 'Site is located in Lenexa. Please review and reconcile ' (Site from CRA).	(b) (4), (b) (6)	22 Dec 2020 17:10:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'Shawnee'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:06:16
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'KS'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:11:06
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered '66219'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:11:07
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 18:23:17
User entered 'US'	System	01 Dec 2020 13:42:35

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	17 Feb 2021 16:06:30
User entered '7'	System	02 Feb 2021 15:58:03
User entered '6'	System	12 Jan 2021 16:47:50
User entered '5'	System	28 Dec 2020 14:02:50
User entered '4'	System	22 Dec 2020 21:36:52
User entered '3'	System	18 Dec 2020 19:39:00
User entered '2'	System	09 Dec 2020 18:23:27
User entered '1'	System	01 Dec 2020 13:42:35

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:01:02

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:40:37
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered '22/Dec/2020 16:36'	(b) (4) System	22 Dec 2020 21:36:52

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:01:02

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)	26 Apr 2021 16:40:37
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:37:06
User entered 'I'	(b) (4), (b) (6)	22 Dec 2020 21:36:52

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:23
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'USA-US300-2020-MRNA-1273-P301000015'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

Serious

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'Yes (Y)'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:28
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'No (N)'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:30
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'No (N)'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'Yes (Y)'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:36
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'No (N)'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:38
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'No (N)'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:42
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'No (N)'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:59
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'Carlos'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:06:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'Fierro'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:06:03
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered '16300 College Blvd'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:39:54
User closed query 'Site is located in Lenexa. Please review and reconcile ' (Site from CRA).	(b) (4), (b) (6)	26 Apr 2021 16:39:52
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
Query 'Site is located in Lenexa. Please review and reconcile ' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	17 Mar 2021 19:45:28
Un-reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 19:45:21
User entered 'Lenexa' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 19:45:21
User opened query 'Site is located in Lenexa. Please review and reconcile ' (Site from CRA).	(b) (4), (b) (6)	22 Dec 2020 17:10:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'Shawnee'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:06:16
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'KS'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:11:06
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered '66219'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:11:07
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 18:23:17
User entered 'US'	System	01 Dec 2020 13:42:35

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	17 Feb 2021 16:06:30
User entered '7'	System	02 Feb 2021 15:58:03
User entered '6'	System	12 Jan 2021 16:47:50
User entered '5'	System	28 Dec 2020 14:02:50
User entered '4'	System	22 Dec 2020 21:36:52
User entered '3'	System	18 Dec 2020 19:39:00
User entered '2'	System	09 Dec 2020 18:23:27
User entered '1'	System	01 Dec 2020 13:42:35

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:01:02

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:40:37
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered '28/Dec/2020 14:02'	(b) (4) System	28 Dec 2020 14:02:50

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:01:02

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)	26 Apr 2021 16:40:37
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:47:36
User entered 'I'	(b) (4), (b) (6)	28 Dec 2020 14:02:50

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:23
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'USA-US300-2020-MRNA-1273-P301000015'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

Serious

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'Yes (Y)'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:28
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'No (N)'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:30
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'No (N)'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'Yes (Y)'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:36
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'No (N)'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:38
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'No (N)'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:42
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'No (N)'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:59
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'Carlos'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:06:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'Fierro'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:06:03
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered '16300 College Blvd'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:39:54
User closed query 'Site is located in Lenexa. Please review and reconcile ' (Site from CRA).	(b) (4), (b) (6)	26 Apr 2021 16:39:52
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
Query 'Site is located in Lenexa. Please review and reconcile ' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	17 Mar 2021 19:45:28
Un-reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 19:45:21
User entered 'Lenexa' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 19:45:21
User opened query 'Site is located in Lenexa. Please review and reconcile ' (Site from CRA).	(b) (4), (b) (6)	22 Dec 2020 17:10:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'Shawnee'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:06:16
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'KS'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:11:06
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered '66219'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:11:07
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 18:23:17
User entered 'US'	System	01 Dec 2020 13:42:35

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	17 Feb 2021 16:06:30
User entered '7'	System	02 Feb 2021 15:58:03
User entered '6'	System	12 Jan 2021 16:47:50
User entered '5'	System	28 Dec 2020 14:02:50
User entered '4'	System	22 Dec 2020 21:36:52
User entered '3'	System	18 Dec 2020 19:39:00
User entered '2'	System	09 Dec 2020 18:23:27
User entered '1'	System	01 Dec 2020 13:42:35

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:01:02

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:40:37
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered '12/Jan/2021 16:47'	(b) (4) System	12 Jan 2021 16:47:50

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:01:02

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)	26 Apr 2021 16:40:37
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 15:58:27
User entered 'I'	(b) (4), (b) (6)	12 Jan 2021 16:47:50

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:23
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'USA-US300-2020-MRNA-1273-P301000015'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

Serious

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'Yes (Y)'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:28
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'No (N)'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:30
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'No (N)'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'Yes (Y)'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:36
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'No (N)'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:38
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'No (N)'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:42
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'No (N)'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:59
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'Carlos'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:06:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'Fierro'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:06:03
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered '16300 College Blvd'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:39:54
User closed query 'Site is located in Lenexa. Please review and reconcile ' (Site from CRA).	(b) (4), (b) (6)	26 Apr 2021 16:39:52
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
Query 'Site is located in Lenexa. Please review and reconcile ' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	17 Mar 2021 19:45:28
Un-reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 19:45:21
User entered 'Lenexa' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 19:45:21
User opened query 'Site is located in Lenexa. Please review and reconcile ' (Site from CRA).	(b) (4), (b) (6)	22 Dec 2020 17:10:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'Shawnee'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:06:16
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'KS'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:11:06
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered '66219'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:11:07
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 18:23:17
User entered 'US'	System	01 Dec 2020 13:42:35

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	17 Feb 2021 16:06:30
User entered '7'	System	02 Feb 2021 15:58:03
User entered '6'	System	12 Jan 2021 16:47:50
User entered '5'	System	28 Dec 2020 14:02:50
User entered '4'	System	22 Dec 2020 21:36:52
User entered '3'	System	18 Dec 2020 19:39:00
User entered '2'	System	09 Dec 2020 18:23:27
User entered '1'	System	01 Dec 2020 13:42:35

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 17:01:02

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:40:37
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered '02/Feb/2021 10:58'	(b) (4) System	02 Feb 2021 15:58:03

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 17:01:02

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)	26 Apr 2021 16:40:37
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 15:58:27
User entered 'I'	(b) (4), (b) (6)	02 Feb 2021 15:58:03

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:23
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'USA-US300-2020-MRNA-1273-P301000015'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

Serious

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'Yes (Y)'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:28
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'No (N)'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:30
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'No (N)'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'Yes (Y)'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:36
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'No (N)'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:38
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'No (N)'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:42
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'No (N)'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:59
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'Carlos'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:06:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'Fierro'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:06:03
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered '16300 College Blvd'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:39:54
User closed query 'Site is located in Lenexa. Please review and reconcile ' (Site from CRA).	(b) (4), (b) (6)	26 Apr 2021 16:39:52
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
Query 'Site is located in Lenexa. Please review and reconcile ' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	17 Mar 2021 19:45:28
Un-reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 19:45:21
User entered 'Lenexa' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 19:45:21
User opened query 'Site is located in Lenexa. Please review and reconcile ' (Site from CRA).	(b) (4), (b) (6)	22 Dec 2020 17:10:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'Shawnee'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:06:16
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered 'KS'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:11:06
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:42:30
User entered '66219'	System	01 Dec 2020 13:42:15

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:11:07
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 18:23:17
User entered 'US'	System	01 Dec 2020 13:42:35

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:01:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	17 Feb 2021 16:06:30
User entered '7'	System	02 Feb 2021 15:58:03
User entered '6'	System	12 Jan 2021 16:47:50
User entered '5'	System	28 Dec 2020 14:02:50
User entered '4'	System	22 Dec 2020 21:36:52
User entered '3'	System	18 Dec 2020 19:39:00
User entered '2'	System	09 Dec 2020 18:23:27
User entered '1'	System	01 Dec 2020 13:42:35

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 17:01:02

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:40:37
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered '17/Feb/2021 11:06'	(b) (4) System	17 Feb 2021 16:06:30

US3312197

Folder: SAE USA-US300-2020-MRNA-1273-P301000015

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 17:01:02

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)	26 Apr 2021 16:40:37
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:14:42
User entered 'I'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 16:06:30