

US3312212 (Prod: Johnson County Clin-Trials)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:02:15

All time stamps listed in this document are displayed in GMT

US3312212

Form: Participant Creation

Data signed: (b) (4) 05 Apr 2021 21:21:25

Generated On: 09 Jun 2021 17:02:15

Participant ID

US3312212

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

US3312212

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 22:09:29

Generated On: 09 Jun 2021 17:02:15

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

Visit date (dd MMM yyyy)	21 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	SCRN
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US3312212

Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 22:09:29

Generated On: 09 Jun 2021 17:02:15

Date of Birth (MMM yyyy)	(b) (6) 1948
Age	71
Age Units	YEARS
Age (Derived)	71
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 22:09:29

Generated On: 09 Jun 2021 17:02:15

Date of Informed Consent (<i>dd MMM yyyy</i>)	21 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

US3312212

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 22:09:29

Generated On: 09 Jun 2021 17:02:15

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 22:09:29

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 15 Feb 2021 22:09:29

Generated On: 09 Jun 2021 17:02:15

Condition	POST MENOPAUSAL
Start date (dd MMM yyyy)	UN OCT 1995
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)	OCT 1995
Start Year (derived)	1995
Stop Month and Year (derived)	
Stop Year (derived)	

US3312212

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Feb 2021 22:09:29

Generated On: 09 Jun 2021 17:02:15

Condition	TYPE II DIABETES MELLITUS
Start date (dd MMM yyyy)	UN UNK 1985
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 1985
Start Year (derived)	1985
Stop Month and Year (derived)	
Stop Year (derived)	

US3312212

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 15 Feb 2021 22:09:29

Generated On: 09 Jun 2021 17:02:15

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

US3312212

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 15 Feb 2021 22:09:29

Generated On: 09 Jun 2021 17:02:15

Condition	RESTLESS LEG SYNDROME
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)	_____

US3312212

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 15 Feb 2021 22:09:29

Generated On: 09 Jun 2021 17:02:15

Condition	RIGHT TOTAL KNEE REPLACEMENT
Start date (dd MMM yyyy)	01 APR 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	01 APR 2000
Stop date completely unknown	False
Start Month and Year (derived)	APR 2000
Start Year (derived)	2000
Stop Month and Year (derived)	APR 2000
Stop Year (derived)	2000

US3312212

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 15 Feb 2021 22:09:29

Generated On: 09 Jun 2021 17:02:15

Condition	LEFT SHOULDER REPLACEMENT
Start date (dd MMM yyyy)	UN UNK 2011
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 2011
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2011
Start Year (derived)	2011
Stop Month and Year (derived)	JAN 2011
Stop Year (derived)	2011

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 15 Feb 2021 22:09:29

Generated On: 09 Jun 2021 17:02:15

Condition	LOWER BACK FUSION
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

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 15 Feb 2021 22:09:29

Generated On: 09 Jun 2021 17:02:15

Condition	RIGHT ROTATOR CUFF REPAIR
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	JAN 1995
Stop Year (derived)	1995

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 15 Feb 2021 22:09:29

Generated On: 09 Jun 2021 17:02:15

Condition	RIGHT ROTATOR CUFF TEAR INJURY
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	JAN 1995
Stop Year (derived)	1995

US3312212

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 15 Feb 2021 22:09:29

Generated On: 09 Jun 2021 17:02:15

Condition	LYMPHADEMA (BILATERAL LOWER EXTREMITIES)
Start date (dd MMM yyyy)	UN NOV 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)	NOV 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 15 Feb 2021 22:09:29

Generated On: 09 Jun 2021 17:02:15

Condition	LEFT SHOULDER FRACTURE
Start date (dd MMM yyyy)	UN UNK 2011
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 2011
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2011
Start Year (derived)	2011
Stop Month and Year (derived)	JAN 2011
Stop Year (derived)	2011

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 15 Feb 2021 22:09:29

Generated On: 09 Jun 2021 17:02:15

Condition	OSTEOARTHRITIS
Start date (dd MMM yyyy)	UN UNK 1998
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 1998
Start Year (derived)	1998
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 15 Feb 2021 22:09:29

Generated On: 09 Jun 2021 17:02:15

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

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 15 Feb 2021 22:09:29

Generated On: 09 Jun 2021 17:02:15

Condition	ALLERGY TO NAPROXEN
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)	_____

US3312212

Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 15 Feb 2021 22:09:29

Generated On: 09 Jun 2021 17:02:15

Condition	LEFT SHOULDER DISLOCATION
Start date (dd MMM yyyy)	UN UNK 2011
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 2011
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2011
Start Year (derived)	2011
Stop Month and Year (derived)	JAN 2011
Stop Year (derived)	2011

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 15 Feb 2021 22:09:29

Generated On: 09 Jun 2021 17:02:15

Condition	STAGE IV CHRONIC RENAL 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)	

US3312212

Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 15 Feb 2021 22:09:29

Generated On: 09 Jun 2021 17:02:15

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

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Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 15 Feb 2021 22:09:29

Generated On: 09 Jun 2021 17:02:15

Condition	VALVULAR HEART 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)	

US3312212

Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 15 Feb 2021 22:09:29

Generated On: 09 Jun 2021 17:02:15

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

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Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) 15 Feb 2021 22:09:29

Generated On: 09 Jun 2021 17:02:15

Condition	OSTEOMYELITIS
Start date (dd MMM yyyy)	UN JUL 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 JUL 2020
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2020
Start Year (derived)	2020
Stop Month and Year (derived)	JUL 2020
Stop Year (derived)	2020

US3312212

Folder: Screening

Form: Medical History (21)

Data signed: (b) (4) 15 Feb 2021 22:09:29

Generated On: 09 Jun 2021 17:02:15

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

US3312212

Folder: Screening

Form: Medical History (22)

Data signed: (b) (4) 15 Feb 2021 22:09:29

Generated On: 09 Jun 2021 17:02:15

Condition	OSTEOTOMY RIGHT FOOT
Start date (dd MMM yyyy)	24 MAY 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	24 MAY 2019
Stop date completely unknown	False
Start Month and Year (derived)	MAY 2019
Start Year (derived)	2019
Stop Month and Year (derived)	MAY 2019
Stop Year (derived)	2019

US3312212

Folder: Screening

Form: Medical History (23)

Data signed: (b) (4) 15 Feb 2021 22:09:29

Generated On: 09 Jun 2021 17:02:15

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

US3312212

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 22:09:29

Generated On: 09 Jun 2021 17:02:15

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	21 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	11:10 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 11:10
Height (<i>xxx.x</i>)	65 in
Weight (<i>xxx.x</i>)	262 lb
BMI (<i>xxx.x</i>)	43.69024 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)	

US3312212

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 22:09:29

Generated On: 09 Jun 2021 17:02:15

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 15 Feb 2021 22:09:29

Generated On: 09 Jun 2021 17:02:15

Date of assessment (*dd MMM yyyy*) 21 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (*dd MMM yyyy*) _____

Date of surgery unknown False

If Post-menopausal, date of last menstruation (*dd MMM yyyy*) UN OCT 1995

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 22:09:29

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 22:09:29

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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

US3312212

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 22:09:29

Generated On: 09 Jun 2021 17:02:15

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

Visit date (dd MMM yyyy)	21 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT1
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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 22:09:29

Generated On: 09 Jun 2021 17:02:15

What was the date of randomization? (dd MMM yyyy) 21 AUG 2020

What was the participant's randomization number? 187336

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 22:09:29

Generated On: 09 Jun 2021 17:02:15

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 22:09:29

Generated On: 09 Jun 2021 17:02:15

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)	21 AUG 2020
Time of assessment (00:00-23:59)	11:10 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 11:10
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)	55 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	50 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 22:09:29

Generated On: 09 Jun 2021 17:02:15

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 AUG 2020
Time of assessment (00:00-23:59)	14:01 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 14:01
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	55 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 22:09:29

Generated On: 09 Jun 2021 17:02:15

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 22:09:29

Generated On: 09 Jun 2021 17:02:15

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) 21 AUG 2020

What was the treatment time? (00:00-23:59) 13:30 (24 HR)

Treatment Date and Time (derived) 21 AUG 2020 13:30

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

US3312212

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 22:09:29

Generated On: 09 Jun 2021 17:02:15

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

21 AUG 2020

Collection time (00:00-23:59)

12:38 (24 HR)

Collection date and time (derived)

21 AUG 2020 12:38

US3312212

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 22:09:29

Generated On: 09 Jun 2021 17:02:15

Collection date (dd MMM yyyy)			21 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:24	21 AUG 2020 12:24
Nasopharyngeal Swab 2	No		

US3312212

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:09:29

Generated On: 09 Jun 2021 17:02:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 AUG 2020 14:09

PC Open Date & Time

21 AUG 2020 13:50

PC Close Date & Time

21 AUG 2020 16:20

US3312212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:02:15

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 97.3 °F

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

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

PC Time Stamp	21 AUG 2020 19:25
PC Open Date & Time	21 AUG 2020 17:15
PC Close Date & Time	22 AUG 2020 11:59

US3312212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 AUG 2020 17:58

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3312212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 AUG 2020 19:15

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3312212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:02:15

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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 21:03

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3312212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

25 AUG 2020 18:05

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3312212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 AUG 2020 21:30

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3312212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

27 AUG 2020 19:20

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3312212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:02:15

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

21 AUG 2020 14:11

PC Open Date & Time

21 AUG 2020 13:50

PC Close Date & Time

21 AUG 2020 16:20

US3312212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:02:15

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

21 AUG 2020 19:27

PC Open Date & Time

21 AUG 2020 17:15

PC Close Date & Time

22 AUG 2020 11:59

US3312212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:02:15

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

22 AUG 2020 17:59

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3312212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:02:15

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

23 AUG 2020 19:16

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3312212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:02:15

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

24 AUG 2020 21:04

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3312212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:02:15

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

25 AUG 2020 18:05

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3312212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:02:15

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

26 AUG 2020 21:31

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3312212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:02:15

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

27 AUG 2020 19:21

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:15

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 ☐

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:15

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

No ☒

Yes ☐

PC Time stamp	21 AUG 2020 14:12
PC Open Date & Time	21 AUG 2020 13:50
PC Close Date & Time	21 AUG 2020 16:20

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:15

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 ☐

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:15

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

No ☒

Yes ☐

PC Time stamp	21 AUG 2020 19:29
PC Open Date & Time	21 AUG 2020 17:15
PC Close Date & Time	22 AUG 2020 11:59

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:15

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 ☒

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:15

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 18:01
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:15

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 19:17
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:15

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 21:05
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:15

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 18:06
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:15

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 21:32
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:15

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

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EAB) (1725)

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:15

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 19:21
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3312212

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:09:16

Generated On: 09 Jun 2021 17:02:15

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 28 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3312212

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:09:16

Generated On: 09 Jun 2021 17:02:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312212

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:09:16

Generated On: 09 Jun 2021 17:02:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312212

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:09:16

Generated On: 09 Jun 2021 17:02:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312212

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:09:16

Generated On: 09 Jun 2021 17:02:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312212

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:09:16

Generated On: 09 Jun 2021 17:02:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312212

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 22:09:29

Generated On: 09 Jun 2021 17:02:15

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3312212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 22:09:29

Generated On: 09 Jun 2021 17:02:15

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	18 SEP 2020
Time of assessment (00:00-23:59)	09:05 (24 HR)
Vital Signs Date and Time (derived)	18 SEP 2020 09:05
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)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	50 mmHg
Diastolic Blood Pressure units	MMHG

US3312212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 22:09:29

Generated On: 09 Jun 2021 17:02:15

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Date of assessment (dd MMM yyyy)	
Time of assessment (00:00-23:59)	
Vital Signs Date and Time (derived)	
Temperature (xxx.x)	
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	
Pulse units	
Respiratory Rate (xxx)	
Respiratory Rate units	
Systolic Blood Pressure (xxx)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (xxx)	
Diastolic Blood Pressure units	

US3312212

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 22:09:29

Generated On: 09 Jun 2021 17:02:15

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 SEP 2020

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

US3312212

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 22:09:29

Generated On: 09 Jun 2021 17:02:15

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?

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?

US3312212

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 22:09:29

Generated On: 09 Jun 2021 17:02:15

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

18 SEP 2020

Collection time (00:00-23:59)

09:44 (24 HR)

Collection date and time (derived)

18 SEP 2020 09:44

US3312212

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 22:09:29

Generated On: 09 Jun 2021 17:02:15

Collection date (dd MMM yyyy)			18 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:36	18 SEP 2020 09:36
Nasopharyngeal Swab 2	No		

US3312212

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:09:29

Generated On: 09 Jun 2021 17:02:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312212

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:09:16

Generated On: 09 Jun 2021 17:02:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312212

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:09:16

Generated On: 09 Jun 2021 17:02:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312212

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:09:16

Generated On: 09 Jun 2021 17:02:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312212

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:09:16

Generated On: 09 Jun 2021 17:02:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312212

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:09:16

Generated On: 09 Jun 2021 17:02:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312212

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:09:16

Generated On: 09 Jun 2021 17:02:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312212

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 22:09:29

Generated On: 09 Jun 2021 17:02:15

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 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

US3312212

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 22:09:29

Generated On: 09 Jun 2021 17:02:15

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	15 OCT 2020
Time of assessment (00:00-23:59)	09:28 (24 HR)
Vital Signs Date and Time (derived)	15 OCT 2020 09:28
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3312212

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 22:09:29

Generated On: 09 Jun 2021 17:02:15

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 OCT 2020

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

US3312212

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 22:09:29

Generated On: 09 Jun 2021 17:02:15

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	15 OCT 2020
Collection time (00:00-23:59)	10:07 (24 HR)
Collection date and time (derived)	15 OCT 2020 10:07

US3312212

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:09:29

Generated On: 09 Jun 2021 17:02:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 OCT 2020 09:15:22

Patient Cloud Open Date & Time

21 OCT 2020 00:01

Patient Cloud Close Date & Time

25 OCT 2020 23:59

US3312212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

29 OCT 2020 15:19:44

Patient Cloud Open Date & Time

28 OCT 2020 00:01

Patient Cloud Close Date & Time

01 NOV 2020 23:59

US3312212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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	05 NOV 2020 15:27:03
Patient Cloud Open Date & Time	04 NOV 2020 00:01
Patient Cloud Close Date & Time	08 NOV 2020 23:59

US3312212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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°F/38°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"/>

US3312212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

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

Date and time of submission

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 NOV 2020 21:16:12
Patient Cloud Open Date & Time	15 NOV 2020 00:01
Patient Cloud Close Date & Time	19 NOV 2020 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 NOV 2020 20:22:32
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

03 DEC 2020 06:40:13

Patient Cloud Open Date & Time

29 NOV 2020 00:01

Patient Cloud Close Date & Time

03 DEC 2020 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

09 DEC 2020 21:15:17

Patient Cloud Open Date & Time

06 DEC 2020 00:01

Patient Cloud Close Date & Time

10 DEC 2020 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

15 DEC 2020 08:33:57

Patient Cloud Open Date & Time

13 DEC 2020 00:01

Patient Cloud Close Date & Time

17 DEC 2020 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

21 DEC 2020 18:53:58

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

28 DEC 2020 12:27:58

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 JAN 2021 14:59:56
Patient Cloud Open Date & Time	03 JAN 2021 00:01
Patient Cloud Close Date & Time	07 JAN 2021 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

10 JAN 2021 13:25:00

Patient Cloud Open Date & Time

10 JAN 2021 00:01

Patient Cloud Close Date & Time

14 JAN 2021 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	19 JAN 2021 08:17:14
Patient Cloud Open Date & Time	17 JAN 2021 00:01
Patient Cloud Close Date & Time	21 JAN 2021 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

26 JAN 2021 21:48:28

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 FEB 2021 16:01:53

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

08 FEB 2021 10:48:22

Patient Cloud Open Date & Time

07 FEB 2021 00:01

Patient Cloud Close Date & Time

11 FEB 2021 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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	15 FEB 2021 00:34:26
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

22 FEB 2021 21:15:45

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

01 MAR 2021 12:07:03

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 MAR 2021 12:58:04
Patient Cloud Open Date & Time	07 MAR 2021 00:01
Patient Cloud Close Date & Time	11 MAR 2021 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

15 MAR 2021 01:29:40

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

21 MAR 2021 16:45:26

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

28 MAR 2021 07:33:00

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

07 APR 2021 16:07:08

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 APR 2021 19:46:12

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

18 APR 2021 10:07:48

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

27 APR 2021 17:37:03

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

03 MAY 2021 06:34:55

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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"/>

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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"/>

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

16 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

DAY 285

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

DAY 292

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

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

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

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

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

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

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

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

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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 ☐

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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 ☐

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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 ☐

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

DAY 334

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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"/>

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

DAY 362

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

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

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

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

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

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

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

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

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

[Patient Cloud Close Date & Time](#)

19 AUG 2021 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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 ☐

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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 ☐

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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 ☐

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

DAY 390

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

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

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

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

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

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

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

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

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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 ☐

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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"/>

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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"/>

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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 ☐

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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"/>

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

DAY 432

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

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

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

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

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

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

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

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

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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 ☐

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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"/>

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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"/>

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

DAY 467

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

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

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

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

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

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

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

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

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

[Patient Cloud Close Date & Time](#)

09 DEC 2021 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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°F/38°C) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

DAY 488

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

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

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

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

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

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

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

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

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	19 DEC 2021 00:01
Patient Cloud Close Date & Time	23 DEC 2021 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 DEC 2021 00:01
Patient Cloud Close Date & Time	30 DEC 2021 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

DAY 502

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

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

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

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

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

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

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

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

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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 ☐

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

DAY 516

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

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

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

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

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

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

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

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

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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 ☐

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

DAY 537

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

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

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

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

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

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

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

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

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 FEB 2022 00:01
Patient Cloud Close Date & Time	10 FEB 2022 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

DAY 544

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

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

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

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

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

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

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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 ☐

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 FEB 2022 00:01
Patient Cloud Close Date & Time	24 FEB 2022 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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 ☐

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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 ☐

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 MAR 2022 00:01
Patient Cloud Close Date & Time	17 MAR 2022 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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 ☐

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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 ☐

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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 ☐

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 APR 2022 00:01
Patient Cloud Close Date & Time	07 APR 2022 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 APR 2022 00:01
Patient Cloud Close Date & Time	14 APR 2022 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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"/>

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 APR 2022 00:01
Patient Cloud Close Date & Time	21 APR 2022 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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"/>

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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"/>

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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"/>

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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 ☐

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

DAY 670

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

DAY 684

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

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

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

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

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

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

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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"/>

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 2022 00:01
Patient Cloud Close Date & Time	14 JUL 2022 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

DAY 698

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

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

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

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

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

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

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

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

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 2022 00:01
Patient Cloud Close Date & Time	21 JUL 2022 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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 ☐

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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"/>

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 2022 00:01
Patient Cloud Close Date & Time	18 AUG 2022 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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"/>

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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 ☐

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

04 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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="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"/>

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

11 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

DAY 768

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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 ☐

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 2022 00:01
Patient Cloud Close Date & Time	06 OCT 2022 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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 ☐

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 2022 00:01
Patient Cloud Close Date & Time	13 OCT 2022 23:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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="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°F/38°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"/>

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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

[Patient Cloud Close Date & Time](#)

27 OCT 2022 23:59

US3312212

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:02:15

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		01 MAR 2021 12:07:29

US3312212

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 21:21:28

Generated On: 09 Jun 2021 17:02:15

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3312212

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:21:28

Generated On: 09 Jun 2021 17:02:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312212

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 21:21:27

Generated On: 09 Jun 2021 17:02:15

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

US3312212

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:21:27

Generated On: 09 Jun 2021 17:02:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312212

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 21:21:28

Generated On: 09 Jun 2021 17:02:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312212

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:21:28

Generated On: 09 Jun 2021 17:02:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312212

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 21:21:28

Generated On: 09 Jun 2021 17:02:15

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 12 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3312212

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:21:28

Generated On: 09 Jun 2021 17:02:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312212

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 21:21:28

Generated On: 09 Jun 2021 17:02:15

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

US3312212

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 21:21:28

Generated On: 09 Jun 2021 17:02:15

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) _____

US3312212

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 21:21:28

Generated On: 09 Jun 2021 17:02:15

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.

US3312212

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 21:21:28

Generated On: 09 Jun 2021 17:02:15

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	09 MAR 2021
Collection time (00:00-23:59)	09:13 (24 HR)
Collection date and time (derived)	09 MAR 2021 09:13

US3312212

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:21:28

Generated On: 09 Jun 2021 17:02:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312212

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 15 Apr 2021 19:58:00

Generated On: 09 Jun 2021 17:02:15

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

US3312212

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 15 Apr 2021 19:58:00

Generated On: 09 Jun 2021 17:02:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312212

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:15

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

US3312212

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:15

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3312212

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:02:15

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

US3312212

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:02:15

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3312212

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

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 21:21:27

Generated On: 09 Jun 2021 17:02:15

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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US3312212

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

Form: Unblinding

Data signed: (b) (4) 05 Apr 2021 21:21:26

Generated On: 09 Jun 2021 17:02:15

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 type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3312212

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 05 Apr 2021 21:21:27

Generated On: 09 Jun 2021 17:02:15

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

US3312212

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Apr 2021 21:21:27

Generated On: 09 Jun 2021 17:02:15

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)	14:10 (24 HR)
Vital Signs Date and Time (derived)	12 JAN 2021 14:10
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	54 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 mmHg
Diastolic Blood Pressure units	MMHG

US3312212

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Apr 2021 21:21:27

Generated On: 09 Jun 2021 17:02:15

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)	15:48 (24 HR)
Vital Signs Date and Time (derived)	12 JAN 2021 15:48
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	55 mmHg
Diastolic Blood Pressure units	MMHG

US3312212

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

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 21:21:26

Generated On: 09 Jun 2021 17:02:15

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.

US3312212

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

Form: Exposure

Data signed: (b) (4) 05 Apr 2021 21:21:26

Generated On: 09 Jun 2021 17:02:15

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) 15:17 (24 HR)

Treatment Date and Time (derived) 12 JAN 2021 15:17

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

US3312212

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 21:21:26

Generated On: 09 Jun 2021 17:02:15

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

12 JAN 2021

Collection time (00:00-23:59)

13:47 (24 HR)

Collection date and time (derived)

12 JAN 2021 13:47

US3312212

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 05 Apr 2021 21:21:26

Generated On: 09 Jun 2021 17:02:15

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)	13:46
Collection Date and Time (derived)	12 JAN 2021 13:46

US3312212

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

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:21:26

Generated On: 09 Jun 2021 17:02:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312212

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 21:21:28

Generated On: 09 Jun 2021 17:02:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312212

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:21:28

Generated On: 09 Jun 2021 17:02:15

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

US3312212

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 21:21:26

Generated On: 09 Jun 2021 17:02:15

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

US3312212

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Apr 2021 21:21:26

Generated On: 09 Jun 2021 17:02:15

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	09 FEB 2021
Time of assessment (00:00-23:59)	13:29 (24 HR)
Vital Signs Date and Time (derived)	09 FEB 2021 13:29
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	55 mmHg
Diastolic Blood Pressure units	MMHG

US3312212

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Apr 2021 21:21:26

Generated On: 09 Jun 2021 17:02:15

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)	09 FEB 2021
Time of assessment (00:00-23:59)	15:03 (24 HR)
Vital Signs Date and Time (derived)	09 FEB 2021 15:03
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)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	58 mmHg
Diastolic Blood Pressure units	MMHG

US3312212

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 21:21:26

Generated On: 09 Jun 2021 17:02:15

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.

US3312212

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 05 Apr 2021 21:21:26

Generated On: 09 Jun 2021 17:02:15

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) 09 FEB 2021

What was the treatment time? (00:00-23:59) 14:32 (24 HR)

Treatment Date and Time (derived) 09 FEB 2021 14:32

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

US3312212

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:21:26

Generated On: 09 Jun 2021 17:02:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312212

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 21:21:28

Generated On: 09 Jun 2021 17:02:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312212

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:21:28

Generated On: 09 Jun 2021 17:02:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312212

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 21:21:26

Generated On: 09 Jun 2021 17:02:15

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

Visit date (dd MMM yyyy)	09 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	OLD57
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US3312212

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 21:21:26

Generated On: 09 Jun 2021 17:02:15

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) _____

US3312212

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 21:21:26

Generated On: 09 Jun 2021 17:02:15

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.

US3312212

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 21:21:26

Generated On: 09 Jun 2021 17:02:15

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	09 MAR 2021
Collection time (00:00-23:59)	09:13 (24 HR)
Collection date and time (derived)	09 MAR 2021 09:13

US3312212

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Mar 2021 15:51:27

Generated On: 09 Jun 2021 17:02:15

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3312212

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Mar 2021 15:51:27

Generated On: 09 Jun 2021 17:02:15

AEID	USA-US300-2020-MRNA-1273-P30 1000002
Adverse event	LEFT GREAT TOE OSTEOMYELITIS
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)	04 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	16 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input 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)	03 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	09 SEP 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Mar 2021 15:51:27

Generated On: 09 Jun 2021 17:02:15

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input checked="" type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	RECOVERED WITH SEQUALAE LEFT GREAT TOE AMPUTATION
Narrative	

US3312212

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Mar 2021 15:51:27

Generated On: 09 Jun 2021 17:02:15

71YR OLD DIABETIC WITH
HISTORY OF LYMPHEDEMA
BILATERAL LOWER
EXTREMITIES, AND CHRONIC
WOUND LEFT GREAT TOE
THOUGHT TO BE NEARLY
RESOLVED BUT
UNFORTUNATELY FOUND TO
HAVE DEEP FISTULA ON
FOLLOW UP 03SEP2020. CT
SCAN 04SEP2020 REVEALED
OSTEOMYELITIS (NOT RELATE
TO STUDY
PRODUCT/PROCEDURE). TOE
AMPUTATION PERFORMED ON
SAME DAY WITH PLANS FOR
HOSPITAL DISCHARGE ON
06SEP2020. SUBJECT REPORTED
FEELING WELL, VOICE AND
MOOD ROBUST ON PHONE,
WILL REQUEST MEDICAL
RECORDS AND FOLLOW.
UPDATE: SUBJECT
DISCHARGED FROM HOSPITAL
09SEP2020-AS HOLIDAY
WEEKEND DELAYED
COLLABORATION WITH HOME
HEALTH AGENCY. HAS PICC
LINE AND RECEIVING IV
ANBTIBIOTICS FOR PLANNED
APPROX 5 WEEKS. SEEING
WOUND CARE SPECIALIST
WEEKLY. MEDICAL RECORDS
PENDING.
UPDATE

US3312212

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Mar 2021 15:51:27

Generated On: 09 Jun 2021 17:02:15

24SEP2020: MEDICAL RECORDS
RECEIVED-CONFIRMED ABOVE.
ALSO MEDICAL HISTORY NOT
PREVIOUSLY REPORTED BY
SUBJECT: STAGE IV CKD,
CHRONIC DIASTOLIC HEART
FAILURE, VALVULAR HEART
DISEASE, NSTEMI, PREVIOUS
OSTEOMYELITIS IN SAME
AREA A FEW MONTHS AGO.
CULTURES ON HOSPITAL
ADMISSION GREW MRSA,
CEFTAROLINE IV VIA PICC
LINE AND DISCHARGED WITH
PICC FOR ANTIBIOTICS X 6
WKS. GLUCOSE RANGED FROM
86-209 DURING
HOSPITALIZATION. VESICULAR
RASH NOTED AT GLUTEAL
CLEFT DIAGNOSED AS ZOSTER
RASH AND TREATED WITH
ORAL ACYCLOVIR. AT DAY 29
STUDY VISIT-SUBJECT WAS
CHEERFUL, ALERT, WEARING
LEFT SURGICAL BOOT, RASH
SCABBED AND DRY VS
STABLE. DOSE 2 WITHHELD.

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

US3312212

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 12 Mar 2021 15:51:27

Generated On: 09 Jun 2021 17:02:15

AEID

Adverse event

HERPES ZOSTER

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)

28 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)

06 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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US3312212

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 12 Mar 2021 15:51:27

Generated On: 09 Jun 2021 17:02:15

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

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 05 Apr 2021 21:21:26

Generated On: 09 Jun 2021 17:02:15

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

Yes ☒

No ☐

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

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 05 Apr 2021 21:21:25

Generated On: 09 Jun 2021 17:02:15

Name of Medication LANTUS

Prophylaxis Yes ☐
No ☒

Indication TYPE II DIABETES MELLITUS

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

NIGHTYL BEFORE BED

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 05 Apr 2021 21:21:25

Generated On: 09 Jun 2021 17:02:15

	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 1990	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 05 Apr 2021 21:21:25

Generated On: 09 Jun 2021 17:02:15

Name of Medication NOVALOG

Prophylaxis Yes ☐
No ☒

Indication TYPE II DIABETES MELLITUS

Dose per administration 28-37

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

If dose unit is Other, specify UNITS

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 05 Apr 2021 21:21:25

Generated On: 09 Jun 2021 17:02:15

	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 1990	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 05 Apr 2021 21:21:25

Generated On: 09 Jun 2021 17:02:15

Name of Medication JARDIANCE

Prophylaxis Yes ☐
No ☒

Indication TYPE II DIABETES MELLITUS

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 05 Apr 2021 21:21:25

Generated On: 09 Jun 2021 17:02:15

	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)	05 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 05 Apr 2021 21:21:25

Generated On: 09 Jun 2021 17:02:15

Name of Medication METOPROLOL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 05 Apr 2021 21:21:25

Generated On: 09 Jun 2021 17:02:15

	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 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 05 Apr 2021 21:21:25

Generated On: 09 Jun 2021 17:02:15

Name of Medication LOSARTAN

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 05 Apr 2021 21:21:25

Generated On: 09 Jun 2021 17:02:15

	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 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 05 Apr 2021 21:21:25

Generated On: 09 Jun 2021 17:02:15

Name of Medication FUROSEMIDE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 05 Apr 2021 21:21:25

Generated On: 09 Jun 2021 17:02:15

	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 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 05 Apr 2021 21:21:25

Generated On: 09 Jun 2021 17:02:15

Name of Medication SPIRONOLACTONE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 12.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 05 Apr 2021 21:21:25

Generated On: 09 Jun 2021 17:02:15

	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 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 05 Apr 2021 21:21:25

Generated On: 09 Jun 2021 17:02:15

Name of Medication PRAMIPEXOLE

Prophylaxis Yes ☐
No ☒

Indication RESTLESS LEG SYNDROME

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 05 Apr 2021 21:21:25

Generated On: 09 Jun 2021 17:02:15

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 05 Apr 2021 21:21:25

Generated On: 09 Jun 2021 17:02:15

Name of Medication BACLOFEN

Prophylaxis Yes ☐
No ☒

Indication RESTLESS LEG SYNDROME

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 05 Apr 2021 21:21:25

Generated On: 09 Jun 2021 17:02:15

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 05 Apr 2021 21:21:25

Generated On: 09 Jun 2021 17:02:15

Name of Medication BACLOFEN

Prophylaxis Yes ☐
No ☒

Indication RESTLESS LEG SYNDROME

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 05 Apr 2021 21:21:25

Generated On: 09 Jun 2021 17:02:15

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 05 Apr 2021 21:21:25

Generated On: 09 Jun 2021 17:02:15

Name of Medication ROSUVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTEROLEMIA

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

THREE TIMES A WEEK

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 05 Apr 2021 21:21:25

Generated On: 09 Jun 2021 17:02:15

	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 2000	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 05 Apr 2021 21:21:25

Generated On: 09 Jun 2021 17:02:15

Name of Medication ACETOMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication OSTEOARTHRITIS

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 ☐

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EAB) (1725)

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 05 Apr 2021 21:21:25

Generated On: 09 Jun 2021 17:02:15

	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 1998	
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"/>

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 05 Apr 2021 21:21:25

Generated On: 09 Jun 2021 17:02:15

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

THREE TIMES PER WEEK

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

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EAB) (1725)

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US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 05 Apr 2021 21:21:25

Generated On: 09 Jun 2021 17:02:15

	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 1995	
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"/>

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 05 Apr 2021 21:21:25

Generated On: 09 Jun 2021 17:02:15

Name of Medication CEFTAROLINE

Prophylaxis Yes ☐
No ☒

Indication LEFT GREAT TOE
OSTEOMYELITIS

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 05 Apr 2021 21:21:25

Generated On: 09 Jun 2021 17:02:15

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	04 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)	15 OCT 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"/>

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 05 Apr 2021 21:21:25

Generated On: 09 Jun 2021 17:02:15

Name of Medication ACYCLOVIR

Prophylaxis Yes ☐
No ☒

Indication HERPES ZOSTER

Dose per administration 800

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

If dose unit is Other, specify

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

If frequency is Other, specify

5 X DAY

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

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EAB) (1725)

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 05 Apr 2021 21:21:25

Generated On: 09 Jun 2021 17:02:15

	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 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)		08 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"/>

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 05 Apr 2021 21:21:25

Generated On: 09 Jun 2021 17:02:15

Name of Medication HYDROCORTISONE 1%

Prophylaxis Yes ☐
No ☒

Indication HERPES ZOSTER

Dose per administration 1

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

If dose unit is Other, specify APPLICATION

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 05 Apr 2021 21:21:25

Generated On: 09 Jun 2021 17:02:15

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		10 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		24 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"/>

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 05 Apr 2021 21:21:25

Generated On: 09 Jun 2021 17:02:15

Name of Medication TRULICITY

Prophylaxis Yes ☐
No ☒

Indication DIABETES MELLITUS TYPE II

Dose per administration 1.5

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

WEEKLY

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 05 Apr 2021 21:21:25

Generated On: 09 Jun 2021 17:02:15

	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)	01 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"/>

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 05 Apr 2021 21:21:25

Generated On: 09 Jun 2021 17:02:15

Name of Medication VITAMIN D3

Prophylaxis Yes ☐
No ☒

Indication HEALTH MAINTENANCE

Dose per administration 1000

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

If dose unit is Other, specify UNITS

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 05 Apr 2021 21:21:25

Generated On: 09 Jun 2021 17:02:15

	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"/>

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 05 Apr 2021 21:21:25

Generated On: 09 Jun 2021 17:02:15

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)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 05 Apr 2021 21:21:25

Generated On: 09 Jun 2021 17:02:15

	Intraocular	<input type="radio"/>
	Intramuscular	<input checked="" 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)	3 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		3 OCT 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"/>

US3312212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 05 Apr 2021 21:21:26

Generated On: 09 Jun 2021 17:02:15

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 05 Apr 2021 21:21:26

Generated On: 09 Jun 2021 17:02:15

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
04 SEP 2020	LEFT GREAT TOE AMPUTATION	Adverse Event	

US3312212

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 07 Apr 2021 18:09:29

Generated On: 09 Jun 2021 17:02:15

Date of dosing discontinuation (dd MMM yyyy) 18 SEP 2020

Primary reason for dosing discontinuation

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

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify SAE#1

US3312212

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:02:15

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 ☐

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Data signed: (b) (4) 05 Apr 2021 21:21:27

Generated On: 09 Jun 2021 17:02:15

SAEID	USA-US300-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Data signed: (b) (4) 05 Apr 2021 21:21:27

Generated On: 09 Jun 2021 17:02:15

SAEID	USA-US300-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	07/SEP/2020 16:52
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Data signed: (b) (4) 05 Apr 2021 21:21:27

Generated On: 09 Jun 2021 17:02:15

SAEID	USA-US300-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	17/SEP/2020 13:09
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

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Data signed: (b) (4) 05 Apr 2021 21:21:27

Generated On: 09 Jun 2021 17:02:15

SAEID	USA-US300-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	24/SEP/2020 08:40
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Data signed: (b) (4) 05 Apr 2021 21:21:27

Generated On: 09 Jun 2021 17:02:15

SAEID	USA-US300-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	07/OCT/2020 14:54
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

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form (6)

Data signed: (b) (4) 05 Apr 2021 21:21:27

Generated On: 09 Jun 2021 17:02:15

SAEID	USA-US300-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	10/NOV/2020 11:36
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

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form (7)

Data signed: (b) (4) 05 Apr 2021 21:21:27

Generated On: 09 Jun 2021 17:02:15

SAEID	USA-US300-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	10/NOV/2020 13:09
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

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form (8)

Data signed: (b) (4) 05 Apr 2021 21:21:27

Generated On: 09 Jun 2021 17:02:15

SAEID	USA-US300-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	25/NOV/2020 12:31
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3312212 (Prod: Johnson County Clin-Trials)

US3312212

Form: Participant Creation

Generated On: 09 Jun 2021 17:02:15

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered 'US3312212'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Aug 2020 16:09:27

US3312212

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:02:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'Yes (Y)'	(b) (4) Christa Estrada (b) (4)	21 Aug 2020 18:39:07

US3312212

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '21 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Aug 2020 16:09:28

US3312212

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'Clinic (Clinic)'	Christa Estrada (b) (4)	21 Aug 2020 18:39:07

US3312212

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:02:15

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered 'SCRN'	System	21 Aug 2020 18:39:07

US3312212

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:02:15

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered (b) (6) 1948' reason for change: Data Entry Error	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 18:00:07
User entered (b) (6) 1945'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Aug 2020 16:09:29

US3312212

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:02:15

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User closed query ' Per DMR: Since the Inclusion/exclusion Criteria Summary form has been updated, kindly consider to complete the demographics form . ' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Aug 2020 19:27:38
Query ' Per DMR: Since the Inclusion/exclusion Criteria Summary form has been updated, kindly consider to complete the demographics form . ' answered with 'updated' (Site from DM).	Karol Moore (b) (4) (b) (4)	28 Aug 2020 16:57:34
User entered '71'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 16:57:28
User opened query ' Per DMR: Since the Inclusion/exclusion Criteria Summary form has been updated, kindly consider to complete the demographics form . ' (Site from DM).	(b) (4), (b) (6)	27 Aug 2020 06:42:55

US3312212

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:02:15

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered 'YEARS'	System	28 Aug 2020 16:57:28

US3312212

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:02:15

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered '71'	System	21 Aug 2020 18:39:47

US3312212

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:02:15

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'Female (F)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 16:57:28

US3312212

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:02:15

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 16:57:28

US3312212

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:02:15

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'I'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 16:57:28

US3312212

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:02:15

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 16:57:28

US3312212

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:02:15

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 16:57:28

US3312212

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:02:15

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 16:57:28

US3312212

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:02:15

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 16:57:28

US3312212

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:02:15

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 16:57:28

US3312212

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:02:15

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered empty.	(b) (4) Karol Moore (b) (4)	28 Aug 2020 16:57:28

US3312212

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:02:15

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 16:57:28

US3312212

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:02:15

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 16:57:28

US3312212

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:02:15

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '21 Aug 2020'	(b) (4) Christa Estrada (b) (4)	21 Aug 2020 18:39:47

US3312212

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered 'Aug 2020'	System	21 Aug 2020 18:39:47

US3312212

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered '2020'	System	21 Aug 2020 18:39:47

US3312212

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:02:15

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'Amendment 2 (2)'	Christa Estrada (b) (4)	21 Aug 2020 18:39:47

US3312212

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'Yes (Y)'	(b) (4) Christa Estrada (b) (4)	21 Aug 2020 18:39:47

US3312212

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered empty.	(b) (4) Christa Estrada (b) (4)	21 Aug 2020 18:39:47

US3312212

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:02:15

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered empty.	(b) (4) Christa Estrada (b) (4)	21 Aug 2020 18:39:47

US3312212

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:02:15

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'No (N)'	(b) (4) Christa Estrada (b) (4)	21 Aug 2020 18:39:47

US3312212

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:02:15

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Aug 2020 16:09:28

US3312212

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:02:15

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered 'I'	System	21 Aug 2020 18:39:47

US3312212

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:02:15

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'Yes (Y)'	(b) (4) Christa Estrada (b) (4)	21 Aug 2020 18:39:17

US3312212

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:02:15

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 16:57:46

US3312212

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:02:15

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 16:59:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 16:59:40
Data point term sent to Coder	System	28 Aug 2020 16:58:40
User entered 'post menopausal'	Karol Moore (b) (4)	28 Aug 2020 16:58:12

US3312212

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'un Oct 1995'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 16:58:12

US3312212

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:02:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 16:58:12

US3312212

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:02:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 16:58:12

US3312212

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:02:15

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered empty.	(b) (4) Karol Moore (b) (4)	28 Aug 2020 16:58:12

US3312212

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:02:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 16:58:12

US3312212

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:02:15

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered 'Oct 1995'	System	28 Aug 2020 16:58:12

US3312212

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:02:15

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered '1995'	System	28 Aug 2020 16:58:12

US3312212

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:02:15

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered empty.	System	28 Aug 2020 16:58:12

US3312212

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:02:15

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered empty.	System	28 Aug 2020 16:58:12

US3312212

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:02:15

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type II diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 16:59:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 16:59:41
Data point term sent to Coder	System	28 Aug 2020 16:58:41
User entered 'type ii diabetes mellitus'	Karol Moore (b) (4)	28 Aug 2020 16:58:29

US3312212

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'un UNK 1985'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 16:58:29

US3312212

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:02:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 16:58:29

US3312212

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:02:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 16:58:29

US3312212

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:02:15

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 16:58:29

US3312212

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:02:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 16:58:29

US3312212

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:02:15

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered 'Jan 1985'	System	28 Aug 2020 16:58:29

US3312212

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:02:15

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered '1985'	System	28 Aug 2020 16:58:29

US3312212

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:02:15

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered empty.	System	28 Aug 2020 16:58:29

US3312212

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:02:15

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered empty.	System	28 Aug 2020 16:58:29

US3312212

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:02:15

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
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 17:00:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 17:00:26
Data point term sent to Coder	System	28 Aug 2020 16:58:41
User entered 'hypertension'	Karol Moore (b) (4)	28 Aug 2020 16:58:40
	(b) (4)	

US3312212

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'un UNK 2015'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 16:58:40

US3312212

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:02:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 16:58:40

US3312212

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:02:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 16:58:40

US3312212

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:02:15

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered empty.	(b) (4) Karol Moore (b) (4)	28 Aug 2020 16:58:40

US3312212

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:02:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 16:58:40

US3312212

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:02:15

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered 'Jan 2015'	System	28 Aug 2020 16:58:40

US3312212

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:02:15

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered '2015'	System	28 Aug 2020 16:58:40

US3312212

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:02:15

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered empty.	System	28 Aug 2020 16:58:40

US3312212

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:02:15

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered empty.	System	28 Aug 2020 16:58:40

US3312212

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:02:15

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Sensory abnormalities NEC, PT: Restless legs syndrome, LLT: Restless leg syndrome - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 17:00:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 17:00:42
Data point term sent to Coder	System	28 Aug 2020 16:59:45
User entered 'restless leg syndrome'	Karol Moore (b) (4)	28 Aug 2020 16:58:54

US3312212

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'un UNK 2010'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 16:58:54

US3312212

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:02:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 16:58:54

US3312212

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:02:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 16:58:54

US3312212

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:02:15

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 16:58:54

US3312212

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:02:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 16:58:54

US3312212

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:02:15

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered 'Jan 2010'	System	28 Aug 2020 16:58:54

US3312212

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:02:15

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered '2010'	System	28 Aug 2020 16:58:54

US3312212

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:02:15

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered empty.	System	28 Aug 2020 16:58:54

US3312212

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:02:15

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered empty.	System	28 Aug 2020 16:58:54

US3312212

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:02:15

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Sep 2020 17:40:02
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'confirmed OA' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 00:41:10
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 17:08:53
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee arthroplasty, LLT: Total knee replacement - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 17:00:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 17:00:42
Data point term sent to Coder	System	28 Aug 2020 16:59:45
User entered 'right total knee replacement'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 16:59:19

US3312212

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '01 Apr 2000'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 16:59:19

US3312212

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:02:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 16:59:19

US3312212

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:02:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 16:59:19

US3312212

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:02:15

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '01 Apr 2000'	(b) (4) Karol Moore (b) (4)	28 Aug 2020 16:59:19

US3312212

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:02:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 16:59:19

US3312212

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:02:15

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered 'Apr 2000'	System	28 Aug 2020 16:59:19

US3312212

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:02:15

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered '2000'	System	28 Aug 2020 16:59:19

US3312212

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:02:15

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered 'Apr 2000'	System	28 Aug 2020 16:59:19

US3312212

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:02:15

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered '2000'	System	28 Aug 2020 16:59:19

US3312212

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:02:15

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Shoulder arthroplasty, LLT: Shoulder replacement - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 17:01:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 17:01:43
Data point term sent to Coder	System	28 Aug 2020 17:00:46
User entered 'left shoulder replacement'	Karol Moore (b) (4)	28 Aug 2020 16:59:47

US3312212

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'un UNK 2011'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 16:59:47

US3312212

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:02:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 16:59:47

US3312212

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:02:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 16:59:47

US3312212

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:02:15

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'un UNK 2011'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 16:59:47

US3312212

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:02:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 16:59:47

US3312212

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:02:15

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered 'Jan 2011'	System	28 Aug 2020 16:59:47

US3312212

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:02:15

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered '2011'	System	28 Aug 2020 16:59:47

US3312212

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:02:15

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered 'Jan 2011'	System	28 Aug 2020 16:59:47

US3312212

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:02:15

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered '2011'	System	28 Aug 2020 16:59:47

US3312212

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:02:15

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Sep 2020 17:40:17
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'confirmed-OA' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 00:42:19
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 17:09:13
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 fusion surgery, LLT: Fusion lumbar spine - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 22:45:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 22:45:49
Data point term sent to Coder	System	28 Aug 2020 17:00:46
User entered 'lower back fusion'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:00:05

US3312212

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'un UNK 2012'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:00:05

US3312212

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:02:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:00:05

US3312212

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:02:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:00:05

US3312212

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:02:15

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'un UNK 2012'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:00:05

US3312212

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:02:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:00:05

US3312212

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:02:15

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered 'Jan 2012'	System	28 Aug 2020 17:00:05

US3312212

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:02:15

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered '2012'	System	28 Aug 2020 17:00:05

US3312212

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:02:15

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered 'Jan 2012'	System	28 Aug 2020 17:00:05

US3312212

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:02:15

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered '2012'	System	28 Aug 2020 17:00:05

US3312212

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:02:15

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
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 17:01:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 17:01:43
Data point term sent to Coder	System	28 Aug 2020 17:00:47
User entered 'right rotator cuff repair'	Karol Moore (b) (4)	28 Aug 2020 17:00:28

US3312212

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'un UNK 1995'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:00:28

US3312212

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:02:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:00:28

US3312212

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:02:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:00:28

US3312212

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:02:15

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'un UNK 1995'	(b) (4) Karol Moore (b) (4)	28 Aug 2020 17:00:28

US3312212

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:02:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:00:28

US3312212

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:02:15

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered 'Jan 1995'	System	28 Aug 2020 17:00:28

US3312212

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:02:15

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered '1995'	System	28 Aug 2020 17:00:28

US3312212

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:02:15

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered 'Jan 1995'	System	28 Aug 2020 17:00:28

US3312212

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:02:15

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered '1995'	System	28 Aug 2020 17:00:28

US3312212

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:02:15

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
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)	29 Aug 2020 07:03:34
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 07:03:34
Data point term sent to Coder	System	28 Aug 2020 17:01:48
User entered 'right rotator cuff tear injury'	Karol Moore (b) (4)	28 Aug 2020 17:01:18

US3312212

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'un UNK 1995'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:01:18

US3312212

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:02:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:01:18

US3312212

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:02:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:01:18

US3312212

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:02:15

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'un UNK 1995'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:01:18

US3312212

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:02:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:01:18

US3312212

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:02:15

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered 'Jan 1995'	System	28 Aug 2020 17:01:18

US3312212

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:02:15

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered '1995'	System	28 Aug 2020 17:01:18

US3312212

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:02:15

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered 'Jan 1995'	System	28 Aug 2020 17:01:18

US3312212

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:02:15

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered '1995'	System	28 Aug 2020 17:01:18

US3312212

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:02:15

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User coded data point as SOC: Vascular disorders, HLT: Lymphatic vessel disorders, HLT: Lymphoedemas, PT: Lymphoedema, LLT: Lymphedema - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 07:51:34
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 07:51:34
Data point term sent to Coder	System	28 Aug 2020 17:02:50
User entered 'lymphadema (bilateral lower extremities)'	Karol Moore (b) (4)	28 Aug 2020 17:02:00

US3312212

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'un Nov 2019'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:02:00

US3312212

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:02:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:02:00

US3312212

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:02:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:02:00

US3312212

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:02:15

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered empty.	(b) (4) Karol Moore (b) (4)	28 Aug 2020 17:02:00

US3312212

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:02:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:02:00

US3312212

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:02:15

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered 'Nov 2019'	System	28 Aug 2020 17:02:00

US3312212

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:02:15

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered '2019'	System	28 Aug 2020 17:02:00

US3312212

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:02:15

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered empty.	System	28 Aug 2020 17:02:00

US3312212

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:02:15

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered empty.	System	28 Aug 2020 17:02:00

US3312212

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:02:15

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User coded data point as SOC: Injury, poisoning and procedural complications, HLT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Upper limb fracture, LLT: Shoulder fracture - version MedDRA\23.0.	Coder Import (b) (4)	24 Sep 2020 16:34:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	24 Sep 2020 16:34:48
Data point term sent to Coder	System	24 Sep 2020 16:34:29
User closed query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' (Site from System).	System	24 Sep 2020 16:33:43
Query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' answered with 'updated' (Site from System).	(b) (4), (b) (6)	24 Sep 2020 16:33:43
User entered 'LEFT SHOULDER FRACTURE' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 16:33:30
User opened query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' (Site from System).	Coder Import (b) (4)	07 Sep 2020 21:48:29
Data point term sent to Coder	System	28 Aug 2020 17:02:53
User entered 'left shoulder fracture/dislocation'	Karol Moore (b) (4)	28 Aug 2020 17:02:49
	(b) (4)	

US3312212

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'un UNK 2011'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:02:49

US3312212

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:02:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:02:49

US3312212

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:02:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	28 Aug 2020 17:02:49

US3312212

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:02:15

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'un UNK 2011'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:02:49

US3312212

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:02:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:02:49

US3312212

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:02:15

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered 'Jan 2011'	System	28 Aug 2020 17:02:49

US3312212

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:02:15

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered '2011'	System	28 Aug 2020 17:02:49

US3312212

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:02:15

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered 'Jan 2011'	System	28 Aug 2020 17:02:49

US3312212

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:02:15

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered '2011'	System	28 Aug 2020 17:02:49

US3312212

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:02:15

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
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)	28 Aug 2020 17:04:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 17:04:39
Data point term sent to Coder	System	28 Aug 2020 17:03:56
User entered 'osteoarthritis'	Karol Moore (b) (4)	28 Aug 2020 17:03:06

US3312212

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'un UNK 1998'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:03:06

US3312212

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:02:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:03:06

US3312212

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:02:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User closed query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	(b) (4) System	25 Sep 2020 00:47:52
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Sep 2020 00:47:52
User opened query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	28 Aug 2020 17:03:06
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:03:06

US3312212

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:02:15

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered empty.	(b) (4) Karol Moore (b) (4)	28 Aug 2020 17:03:06

US3312212

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:02:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:03:06

US3312212

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:02:15

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered 'Jan 1998'	System	28 Aug 2020 17:03:06

US3312212

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:02:15

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered '1998'	System	28 Aug 2020 17:03:06

US3312212

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:02:15

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered empty.	System	28 Aug 2020 17:03:06

US3312212

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:02:15

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered empty.	System	28 Aug 2020 17:03:06

US3312212

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:02:15

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 17:04:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 17:04:39
Data point term sent to Coder	System	28 Aug 2020 17:03:56
User entered 'hypercholesterolemia'	Karol Moore (b) (4)	28 Aug 2020 17:03:21

US3312212

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'un UNK 2000'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:03:21

US3312212

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:02:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:03:21

US3312212

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:02:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	28 Aug 2020 17:03:21

US3312212

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:02:15

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered empty.	(b) (4) Karol Moore (b) (4)	28 Aug 2020 17:03:21

US3312212

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:02:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:03:21

US3312212

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:02:15

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered 'Jan 2000'	System	28 Aug 2020 17:03:21

US3312212

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:02:15

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered '2000'	System	28 Aug 2020 17:03:21

US3312212

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:02:15

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered empty.	System	28 Aug 2020 17:03:21

US3312212

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:02:15

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered empty.	System	28 Aug 2020 17:03:21

US3312212

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:02:15

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 17:07:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 17:07:57
Data point term sent to Coder	System	28 Aug 2020 17:07:03
User entered 'allergy to naproxen'	Karol Moore (b) (4)	28 Aug 2020 17:06:33

US3312212

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'un UNK 2010'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:06:33

US3312212

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:02:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:06:33

US3312212

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:02:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:06:33

US3312212

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:02:15

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered empty.	(b) (4) Karol Moore (b) (4)	28 Aug 2020 17:06:33

US3312212

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:02:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:06:33

US3312212

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:02:15

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered 'Jan 2010'	System	28 Aug 2020 17:06:33

US3312212

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:02:15

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered '2010'	System	28 Aug 2020 17:06:33

US3312212

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:02:15

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered empty.	System	28 Aug 2020 17:06:33

US3312212

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:02:15

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered empty.	System	28 Aug 2020 17:06:33

US3312212

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:02:15

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Fractures and dislocations NEC, PT: Joint dislocation, LLT: Shoulder dislocation - version MedDRA\\23.0.	Coder Import (b) (4)	24 Sep 2020 16:34:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Sep 2020 16:34:48
Data point term sent to Coder	System	24 Sep 2020 16:34:29
User entered 'Left shoulder dislocation'	(b) (4), (b) (6)	24 Sep 2020 16:34:14

US3312212

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'un UNK 2011'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 16:34:14

US3312212

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:02:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 16:34:14

US3312212

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:02:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 16:34:14

US3312212

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:02:15

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'un UNK 2011'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 16:34:14

US3312212

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:02:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 16:34:14

US3312212

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:02:15

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered 'Jan 2011'	System	24 Sep 2020 16:34:14

US3312212

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:02:15

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered '2011'	System	24 Sep 2020 16:34:14

US3312212

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:02:15

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered 'Jan 2011'	System	24 Sep 2020 16:34:14

US3312212

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:02:15

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered '2011'	System	24 Sep 2020 16:34:14

US3312212

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:02:15

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User closed query 'Per MM, please review and confirm if this is a stable condition not requiring significant change in therapy or hospitalization for worsening disease during the 3 months before enrollment.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 10:59:36
Query 'Per MM, please review and confirm if this is a stable condition not requiring significant change in therapy or hospitalization for worsening disease during the 3 months before enrollment.' answered with 'not previously reported prior to enrollment' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 22:38:03
User opened query 'Per MM, please review and confirm if this is a stable condition not requiring significant change in therapy or hospitalization for worsening disease during the 3 months before enrollment.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 16:18:43
User coded data point as SOC: Renal and urinary disorders, HLGT: Renal disorders (excl nephropathies), HLT: Renal failure and impairment, PT: Chronic kidney disease, LLT: Chronic kidney disease stage 4 - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Sep 2020 05:34:38
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Sep 2020 05:34:38
Data point term sent to Coder	System	25 Sep 2020 00:43:19
User entered 'Stage IV Chronic Renal disease'	(b) (4), (b) (6)	25 Sep 2020 00:42:56

US3312212

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'un UNK 2018'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 00:42:56

US3312212

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:02:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 00:42:56

US3312212

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:02:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 00:42:56

US3312212

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:02:15

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 00:42:56

US3312212

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:02:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 00:42:56

US3312212

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:02:15

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered 'Jan 2018'	System	25 Sep 2020 00:42:56

US3312212

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:02:15

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered '2018'	System	25 Sep 2020 00:42:56

US3312212

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:02:15

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered empty.	System	25 Sep 2020 00:42:56

US3312212

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:02:15

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered empty.	System	25 Sep 2020 00:42:56

US3312212

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:02:15

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User coded data point as SOC: Cardiac disorders, HLT: Left ventricular failures, PT: Chronic left ventricular failure, LLT: Chronic diastolic heart failure - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 00:45:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 00:45:48
Data point term sent to Coder	System	25 Sep 2020 00:44:20
User entered 'chronic diastolic heart failure'	(b) (4), (b) (6)	25 Sep 2020 00:43:21

US3312212

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'un UNK 2016'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 00:43:21

US3312212

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:02:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 00:43:21

US3312212

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:02:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 00:43:21

US3312212

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:02:15

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 00:43:21

US3312212

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:02:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 00:43:21

US3312212

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:02:15

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered 'Jan 2016'	System	25 Sep 2020 00:43:21

US3312212

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:02:15

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered '2016'	System	25 Sep 2020 00:43:21

US3312212

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:02:15

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered empty.	System	25 Sep 2020 00:43:21

US3312212

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:02:15

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered empty.	System	25 Sep 2020 00:43:21

US3312212

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:02:15

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User coded data point as SOC: Cardiac disorders, HLT: Cardiac valve disorders, HLT: Cardiac valve disorders NEC, PT: Cardiac valve disease, LLT: Valvular heart disease NOS - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 00:45:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 00:45:48
Data point term sent to Coder	System	25 Sep 2020 00:44:20
User entered 'valvular heart disease'	(b) (4), (b) (6)	25 Sep 2020 00:43:39

US3312212

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'un UNK 2017'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 00:43:39

US3312212

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:02:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 00:43:39

US3312212

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:02:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 00:43:39

US3312212

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:02:15

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 00:43:39

US3312212

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:02:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 00:43:39

US3312212

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:02:15

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered 'Jan 2017'	System	25 Sep 2020 00:43:39

US3312212

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:02:15

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered '2017'	System	25 Sep 2020 00:43:39

US3312212

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:02:15

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered empty.	System	25 Sep 2020 00:43:39

US3312212

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:02:15

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered empty.	System	25 Sep 2020 00:43:39

US3312212

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:02:15

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User coded data point as SOC: Cardiac disorders, HLT: Ischaemic coronary artery disorders, PT: Acute myocardial infarction, LLT: Non ST segment elevation myocardial infarction - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 06:01:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 06:01:40
Data point term sent to Coder	System	25 Sep 2020 00:45:20
User entered 'non ST elevation myocardial infarction'	(b) (4), (b) (6)	25 Sep 2020 00:44:38

US3312212

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'un UNK 2017'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 00:44:38

US3312212

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:02:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 00:44:38

US3312212

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:02:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	25 Sep 2020 00:47:22
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Sep 2020 00:47:22
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Sep 2020 00:47:22
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Sep 2020 00:44:38
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 00:44:38

US3312212

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:02:15

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'un UNK 2017'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 00:44:38

US3312212

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:02:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 00:44:38

US3312212

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:02:15

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered 'Jan 2017'	System	25 Sep 2020 00:44:38

US3312212

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:02:15

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered '2017'	System	25 Sep 2020 00:44:38

US3312212

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:02:15

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered 'Jan 2017'	System	25 Sep 2020 00:44:38

US3312212

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:02:15

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered '2017'	System	25 Sep 2020 00:44:38

US3312212

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:02:15

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Bone and joint infections, PT: Osteomyelitis, LLT: Osteomyelitis - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 00:45:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 00:45:48
Data point term sent to Coder	System	25 Sep 2020 00:45:20
User entered 'osteomyelitis'	(b) (4), (b) (6)	25 Sep 2020 00:45:09

US3312212

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'un Jul 2020'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 00:45:09

US3312212

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:02:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 00:45:09

US3312212

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:02:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 00:45:09

US3312212

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:02:15

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'un Jul 2020'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 00:45:09

US3312212

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:02:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 00:45:09

US3312212

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:02:15

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered 'Jul 2020'	System	25 Sep 2020 00:45:09

US3312212

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:02:15

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered '2020'	System	25 Sep 2020 00:45:09

US3312212

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:02:15

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered 'Jul 2020'	System	25 Sep 2020 00:45:09

US3312212

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:02:15

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered '2020'	System	25 Sep 2020 00:45:09

US3312212

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:02:15

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Wound, LLT: Wound - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 06:29:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 06:29:45
Data point term sent to Coder	System	25 Sep 2020 00:47:21
User entered 'chronic wound left toe'	(b) (4), (b) (6)	25 Sep 2020 00:46:53

US3312212

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'un UNK 2020'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 00:46:53

US3312212

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:02:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 00:46:53

US3312212

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:02:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 00:46:53

US3312212

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:02:15

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 00:46:53

US3312212

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:02:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 00:46:53

US3312212

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:02:15

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered 'Jan 2020'	System	25 Sep 2020 00:46:53

US3312212

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:02:15

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered '2020'	System	25 Sep 2020 00:46:53

US3312212

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:02:15

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered empty.	System	25 Sep 2020 00:46:53

US3312212

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:02:15

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered empty.	System	25 Sep 2020 00:46:53

US3312212

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:02:15

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Bone therapeutic procedures NEC, PT: Osteotomy, LLT: Osteotomy - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 05:57:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 05:57:47
Data point term sent to Coder	System	25 Sep 2020 01:09:39
User entered 'osteotomy right foot'	(b) (4), (b) (6)	25 Sep 2020 01:09:12

US3312212

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '24 May 2019'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 01:09:12

US3312212

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:02:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 01:09:12

US3312212

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:02:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 01:09:12

US3312212

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:02:15

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '24 May 2019'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 01:09:12

US3312212

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:02:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 01:09:12

US3312212

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:02:15

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered 'May 2019'	System	25 Sep 2020 01:09:12

US3312212

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:02:15

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered '2019'	System	25 Sep 2020 01:09:12

US3312212

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:02:15

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered 'May 2019'	System	25 Sep 2020 01:09:12

US3312212

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:02:15

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered '2019'	System	25 Sep 2020 01:09:12

US3312212

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:02:15

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Wound, LLT: Wound - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 05:42:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 05:42:45
Data point term sent to Coder	System	25 Sep 2020 01:10:40
User entered 'recurrent right foot wound'	(b) (4), (b) (6)	25 Sep 2020 01:09:44

US3312212

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'un UNK 2016'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 01:09:44

US3312212

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:02:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 01:09:44

US3312212

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:02:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 01:09:44

US3312212

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:02:15

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'un UNK 2016'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 01:09:44

US3312212

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:02:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 01:09:44

US3312212

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:02:15

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered 'Jan 2016'	System	25 Sep 2020 01:09:44

US3312212

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:02:15

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered '2016'	System	25 Sep 2020 01:09:44

US3312212

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:02:15

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered 'Jan 2016'	System	25 Sep 2020 01:09:44

US3312212

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:02:15

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered '2016'	System	25 Sep 2020 01:09:44

US3312212

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:07:53

US3312212

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '21 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:07:53

US3312212

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:15

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '11:10'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:07:53

US3312212

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:15

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered '21 Aug 2020 11:10'	System	28 Aug 2020 17:07:53

US3312212

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:15

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '65' in	(b) (4) Karol Moore (b) (4)	28 Aug 2020 17:07:53
DataPoint set to visible.	(b) (4) System	21 Aug 2020 18:39:47

US3312212

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:15

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '262' lb	(b) (4) Karol Moore (b) (4)	28 Aug 2020 17:07:53
DataPoint set to visible.	(b) (4) System	21 Aug 2020 18:39:47

US3312212

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:15

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
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 06:25:01
Query 'Per CDM: per sponsor review, BMI \geq 40 kg/m2 yet Severe obesity = No in Randomization Form. Please reconcile.' answered with 'NA. CRITERIA SHOULD ONLY BE SELECTED FOR SUBJECTS BETWEEN AGES OF 18 AND 65. SUBJECTS OVER 65 ARE AUTOMATICALLY ADDED TO AT RISK COHORT' (Site from DM).	Karol Moore (b) (4) (b) (4)	07 Apr 2021 16:35:57
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 05:33:33
User entered '43.69024'	System	28 Aug 2020 17:07:53
DataPoint set to visible.	System	21 Aug 2020 18:39:47

US3312212

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:15

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered 'kg/m2'	System	28 Aug 2020 17:07:53
DataPoint set to visible.	System	21 Aug 2020 18:39:47

US3312212

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:07:53

US3312212

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:07:53

US3312212

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered empty.	(b) (4) Karol Moore (b) (4)	28 Aug 2020 17:07:53

US3312212

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	28 Aug 2020 17:07:53

US3312212

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered 'bpm'	System	28 Aug 2020 17:07:53

US3312212

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	28 Aug 2020 17:07:53

US3312212

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered 'breaths/min'	System	28 Aug 2020 17:07:53

US3312212

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:15

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	28 Aug 2020 17:07:53

US3312212

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered 'mmHg'	System	28 Aug 2020 17:07:53

US3312212

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	28 Aug 2020 17:07:53

US3312212

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:15

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User entered 'mmHg'	System	28 Aug 2020 17:07:53

US3312212

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:15

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33

US3312212

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:15

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33

US3312212

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:02:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:08:20

US3312212

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:02:15

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '21 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:08:20

US3312212

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:02:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '21 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:08:44

US3312212

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:02:15

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	28 Aug 2020 17:08:44

US3312212

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:02:15

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Karol Moore (b) (4)	28 Aug 2020 17:08:44

US3312212

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:02:15

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered empty.	(b) (4) Karol Moore (b) (4)	28 Aug 2020 17:08:44

US3312212

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:02:15

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:08:44

US3312212

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:02:15

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:08:44

US3312212

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'un Oct 1995'	(b) (4) Karol Moore (b) (4)	28 Aug 2020 17:08:44

US3312212

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:02:15

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:08:44

US3312212

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:15

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 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:09:16

US3312212

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:15

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 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:09:16

US3312212

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:15

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 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:09:16

US3312212

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:15

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 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:09:16

US3312212

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:15

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 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	28 Aug 2020 17:09:16

US3312212

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:15

[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 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	28 Aug 2020 17:09:16

US3312212

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:15

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 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:09:16

US3312212

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:15

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 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	28 Aug 2020 17:09:16

US3312212

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:15

[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 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	28 Aug 2020 17:09:16

US3312212

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:15

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 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:09:16

US3312212

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:15

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 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	28 Aug 2020 17:09:16

US3312212

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:15

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	28 Aug 2020 17:09:16

US3312212

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:15

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:09:16

US3312212

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:15

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:09:16

US3312212

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:15

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:09:16

US3312212

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:15

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 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:09:16

US3312212

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:15

[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 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '0'	(b) (4) Karol Moore (b) (4)	28 Aug 2020 17:09:16

US3312212

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:15

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 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:09:16

US3312212

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:15

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '0'	(b) (4) Karol Moore (b) (4)	28 Aug 2020 17:09:16

US3312212

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:15

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'I'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:09:16

US3312212

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:02:15

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:03:33
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'resides in community with ongoing person to person transmission'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:09:16

US3312212

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:02:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'Yes (Y)'	(b) (4) Christa Estrada (b) (4)	21 Aug 2020 18:39:58

US3312212

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '21 Aug 2020'	(b) (4) Christa Estrada (b) (4)	21 Aug 2020 18:39:58

US3312212

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:02:15

[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 11:32:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'Clinic (Clinic)'	Christa Estrada (b) (4)	21 Aug 2020 18:39:58

US3312212

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:02:15

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User entered 'VISIT1'	System	21 Aug 2020 18:39:58

US3312212

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '21 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Aug 2020 18:14:17

US3312212

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:02:15

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '187336'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Aug 2020 18:14:17

US3312212

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:02:15

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Aug 2020 18:14:17

US3312212

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:02:15

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 11:32:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'No (N)'	Christa Estrada (b) (4)	21 Aug 2020 18:40:08

US3312212

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:02:15

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 11:32:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'No (N)'	Christa Estrada (b) (4)	21 Aug 2020 18:40:08

US3312212

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:02:15

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'No (N)'	(b) (4) Christa Estrada (b) (4)	21 Aug 2020 18:40:08

US3312212

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:02:15

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'No (N)'	(b) (4) Christa Estrada (b) (4)	21 Aug 2020 18:40:08

US3312212

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:02:15

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'No (N)'	(b) (4) Christa Estrada (b) (4)	21 Aug 2020 18:40:08

US3312212

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:02:15

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:02:12
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:38:16
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 02:00:43

US3312212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:02:15

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:10:08

US3312212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:02:15

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	28 Aug 2020 17:10:08
	(b) (4)	

US3312212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:02:15

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:10:08

US3312212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:02:15

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:10:08

US3312212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:15

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User accepted default value 'Pre-Dose (PREDOSE)'	Karol Moore (b) (4)	28 Aug 2020 17:10:08
	(b) (4)	

US3312212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:10:08

US3312212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '21 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:10:08

US3312212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:15

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '11:10'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:10:08

US3312212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:15

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User entered '21 Aug 2020 11:10'	System	28 Aug 2020 17:10:08

US3312212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '98.1' F	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:10:08

US3312212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:10:08

US3312212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:10:08

US3312212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '55'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:10:08

US3312212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User entered 'bpm'	System	28 Aug 2020 17:10:08

US3312212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '16'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:10:08

US3312212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User entered 'breaths/min'	System	28 Aug 2020 17:10:08

US3312212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '113'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:10:08

US3312212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User entered 'mmHg'	System	28 Aug 2020 17:10:08

US3312212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
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)	25 Sep 2020 10:21:26
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS and predose therefore no AE' (Site from System).	(b) (4), (b) (6)	25 Sep 2020 00:48:25
Amendment Manager: 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	17 Sep 2020 00:18:21
User entered '50'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:10:08

US3312212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:15

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User entered 'mmHg'	System	28 Aug 2020 17:10:08

US3312212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:02:15

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:10:08

US3312212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:02:15

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:10:08

US3312212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:15

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User accepted default value 'Post-Dose (POSTDOSE)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:10:08

US3312212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:10:08

US3312212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '21 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:10:08

US3312212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:15

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '14:01'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:10:08

US3312212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:15

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User entered '21 Aug 2020 14:01'	System	28 Aug 2020 17:10:08

US3312212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '97.9' F	(b) (4)	28 Aug 2020 17:10:08
	Karol Moore (b) (4)	
	(b) (4)	

US3312212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:10:08

US3312212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:10:08

US3312212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '58'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:10:08

US3312212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User entered 'bpm'	System	28 Aug 2020 17:10:08

US3312212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '16'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:10:08

US3312212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User entered 'breaths/min'	System	28 Aug 2020 17:10:08

US3312212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '125'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:10:08

US3312212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User entered 'mmHg'	System	28 Aug 2020 17:10:08

US3312212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User closed query 'Per CDM: Thank you for your response. However, please indicate if PI considers diastolic blood pressure NCS or CS and record AE if applicable. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Oct 2020 12:00:55
Query 'Per CDM: Thank you for your response. However, please indicate if PI considers diastolic blood pressure NCS or CS and record AE if applicable. Thank you' answered with 'Correct as entered NCS. Not an AE. Per protocol toxicity table, diastolic blood pressure not defined.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 20:02:46
User opened query 'Per CDM: Thank you for your response. However, please indicate if PI considers diastolic blood pressure NCS or CS and record AE if applicable. Thank you' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 18:30:58
User closed query 'Per CDM: Please indicate if NCS or CS and report AE if necessary. Thank you.' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 18:28:38
Query 'Per CDM: Please indicate if NCS or CS and report AE if necessary. Thank you.' answered with 'CORRECT AS ENTERED. PER PROTOCOL TOXICITY TABLE DIASTOLIC BLOOD PRESSURE IS NOT DEFINED' (Site from DM).	Karol Moore (b) (4) (b) (4)	07 Oct 2020 00:26:40
User opened query 'Per CDM: Please indicate if NCS or CS and report AE if necessary. Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 13:02:51
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	25 Sep 2020 13:01:50
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 'diastolic hypotension not on tox table' (Site from System).	(b) (4), (b) (6)	25 Sep 2020 00:49:13

US3312212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Amendment Manager: 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). User entered '55'	System	17 Sep 2020 00:18:21
	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:10:08

US3312212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:15

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User entered 'mmHg'	System	28 Aug 2020 17:10:08

US3312212

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:02:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	28 Aug 2020 17:10:14

US3312212

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:02:15

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:10:14

US3312212

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:02:15

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'Yes (Y)'	(b) (4) Christa Estrada (b) (4)	21 Aug 2020 18:40:36

US3312212

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:02:15

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered empty.	(b) (4) Christa Estrada (b) (4)	21 Aug 2020 18:40:36

US3312212

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:02:15

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 11:32:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered empty.	Christa Estrada (b) (4)	21 Aug 2020 18:40:36

US3312212

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:02:15

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User entered 'MRNA-1273 OR PLACEBO'	System	21 Aug 2020 18:40:36

US3312212

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:02:15

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '21 Aug 2020'	(b) (4) Christa Estrada (b) (4)	21 Aug 2020 18:40:36

US3312212

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:02:15

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '13:30'	(b) (4) Christa Estrada (b) (4)	21 Aug 2020 18:40:36

US3312212

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:02:15

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User entered '21 Aug 2020 13:30'	System	21 Aug 2020 18:40:36

US3312212

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:02:15

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'Left Arm (LEFT ARM)'	Christa Estrada (b) (4)	21 Aug 2020 18:40:36

US3312212

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:02:15

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User entered 'ONCE'	System	21 Aug 2020 18:40:36

US3312212

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:02:15

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User entered 'INTRAMUSCULAR'	System	21 Aug 2020 18:40:36

US3312212

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:15

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User closed query 'Was the sample collected? is No, however Date and/or Time is present. Please correct.' (Site from System).	(b) (4)	28 Aug 2020 17:10:48
User entered 'Yes (Y)' reason for change: Data Entry Error	Karol Moore (b) (4)	28 Aug 2020 17:10:48
User opened query 'Was the sample collected? is No, however Date and/or Time is present. Please correct.' (Site from System).	(b) (4)	28 Aug 2020 17:10:43
User entered 'No (N)'	Karol Moore (b) (4)	28 Aug 2020 17:10:43
	(b) (4)	

US3312212

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:15

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '21 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:10:43

US3312212

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:15

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '12:38'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:10:43

US3312212

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:15

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User entered '21 Aug 2020 12:38'	System	28 Aug 2020 17:10:43

US3312212

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:02:15

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '21 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:10:57

US3312212

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:02:15

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:10:57

US3312212

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:02:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:10:57

US3312212

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:02:15

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '12:24'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:10:57

US3312212

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:02:15

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User entered '21 Aug 2020 12:24'	System	28 Aug 2020 17:10:57

US3312212

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:02:15

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:10:57

US3312212

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:02:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:10:57

US3312212

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:02:15

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:10:57

US3312212

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:02:15

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User entered empty.	System	28 Aug 2020 17:10:57

US3312212

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:02:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:11:02

US3312212

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:02:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User entered 'I'	System	28 Aug 2020 17:11:02

US3312212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
Data entry locked.	System	21 Aug 2020 18:40:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 18:40:36

US3312212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:02:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-21T14:09:15', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '66eb4044-8309-48fb-90f4-2ef2066d7b95'	System	21 Aug 2020 19:09:58
User entered 'Yes (Y)'	System	21 Aug 2020 19:09:58

US3312212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:02:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-21T14:09:32', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '66eb4044-8309-48fb-90f4-2ef2066d7b95'	System	21 Aug 2020 19:09:58
User entered '97.9'	System	21 Aug 2020 19:09:58

US3312212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-21T14:09:42', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '66eb4044-8309-48fb-90f4-2ef2066d7b95'	System	21 Aug 2020 19:09:58
User entered 'No (N)'	System	21 Aug 2020 19:09:58

US3312212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:02:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-21T14:09:53', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '66eb4044-8309-48fb-90f4-2ef2066d7b95'	System	21 Aug 2020 19:09:58
User entered '21 Aug 2020 14:09'	System	21 Aug 2020 19:09:58

US3312212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:02:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
User entered '21 Aug 2020 13:50'	System	21 Aug 2020 18:40:36

US3312212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:02:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
User entered '21 Aug 2020 16:20'	System	21 Aug 2020 18:40:36

US3312212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
Data entry locked.	System	21 Aug 2020 18:40:36
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 18:40:36

US3312212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:02:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-21T19:25:24', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'e4277d24-4ef4-491f-98c5-2b54f1078621' User entered 'Yes (Y)'	System	22 Aug 2020 00:25:56
	System	22 Aug 2020 00:25:56

US3312212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:02:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-21T19:25:35', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'e4277d24-4ef4-491f-98c5-2b54f1078621' User entered '97.3'	System	22 Aug 2020 00:25:56
	System	22 Aug 2020 00:25:56

US3312212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-21T19:25:41', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'e4277d24-4ef4-491f-98c5-2b54f1078621' User entered 'No (N)'	System	22 Aug 2020 00:25:56
	System	22 Aug 2020 00:25:56

US3312212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:02:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-21T19:25:54', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'e4277d24-4ef4-491f-98c5-2b54f1078621' User entered '21 Aug 2020 19:25'	System	22 Aug 2020 00:25:56
	System	22 Aug 2020 00:25:56

US3312212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:02:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
User entered '21 Aug 2020 17:15'	System	21 Aug 2020 18:40:36

US3312212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:02:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 18:40:36

US3312212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
Data entry locked.	System	21 Aug 2020 18:40:36
User entered 'Day 2'	System	21 Aug 2020 18:40:36

US3312212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:02:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-22T17:57:38', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'fd55b4d5-f40f-4773-8345-3c02b100d79d' User entered 'Yes (Y)'	System	22 Aug 2020 22:58:50
	System	22 Aug 2020 22:58:50

US3312212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:02:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-22T17:58:25', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'fd55b4d5-f40f-4773-8345-3c02b100d79d' User entered '98.4'	System	22 Aug 2020 22:58:50
	System	22 Aug 2020 22:58:50

US3312212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-22T17:58:34', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'fd55b4d5-f40f-4773-8345-3c02b100d79d' User entered 'No (N)'	System	22 Aug 2020 22:58:50
	System	22 Aug 2020 22:58:50

US3312212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:02:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-22T17:58:48', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'fd55b4d5-f40f-4773-8345-3c02b100d79d' User entered '22 Aug 2020 17:58'	System	22 Aug 2020 22:58:50
	System	22 Aug 2020 22:58:50

US3312212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:02:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 18:40:36

US3312212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:02:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 18:40:36

US3312212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
Data entry locked.	System	21 Aug 2020 18:40:36
User entered 'Day 3'	System	21 Aug 2020 18:40:36

US3312212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:02:15

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-23T19:14:55', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'b776799c-ae78-4d19-95cc-4bab626fac3b' User entered 'Yes (Y)'	System	24 Aug 2020 00:15:38
	System	24 Aug 2020 00:15:38

US3312212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:02:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-23T19:15:20', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'b776799c-ae78-4d19-95cc-4bab626fac3b' User entered '97.2'	System	24 Aug 2020 00:15:38
	System	24 Aug 2020 00:15:38

US3312212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-23T19:15:26', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'b776799c-ae78-4d19-95cc-4bab626fac3b' User entered 'No (N)'	System	24 Aug 2020 00:15:38
	System	24 Aug 2020 00:15:38

US3312212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:02:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-23T19:15:36', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'b776799c-ae78-4d19-95cc-4bab626fac3b' User entered '23 Aug 2020 19:15'	System	24 Aug 2020 00:15:38
	System	24 Aug 2020 00:15:38

US3312212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:02:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 18:40:36

US3312212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:02:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 18:40:36

US3312212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
Data entry locked.	System	21 Aug 2020 18:40:36
User entered 'Day 4'	System	21 Aug 2020 18:40:36

US3312212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:02:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-24T21:02:38', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '51c00b78-5625-4b60-b879-b55432735532'	System	25 Aug 2020 02:03:06
User entered 'Yes (Y)'	System	25 Aug 2020 02:03:06

US3312212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:02:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-24T21:02:46', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '51c00b78-5625-4b60-b879-b55432735532' User entered '98.0'	System	25 Aug 2020 02:03:06
	System	25 Aug 2020 02:03:06

US3312212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-24T21:02:54', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '51c00b78-5625-4b60-b879-b55432735532'	System	25 Aug 2020 02:03:06
User entered 'No (N)'	System	25 Aug 2020 02:03:06

US3312212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:02:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-24T21:03:02', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '51c00b78-5625-4b60-b879-b55432735532' User entered '24 Aug 2020 21:03'	System	25 Aug 2020 02:03:06
	System	25 Aug 2020 02:03:06

US3312212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:02:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
User entered '24 Aug 2020 12:00'	System	21 Aug 2020 18:40:36

US3312212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:02:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
User entered '25 Aug 2020 11:59'	System	21 Aug 2020 18:40:36

US3312212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
Data entry locked.	System	21 Aug 2020 18:40:36
User entered 'Day 5'	System	21 Aug 2020 18:40:36

US3312212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:02:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-25T18:04:35', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '8e4d13f4-b45e-4462-93cc-e031bb19267c' User entered 'Yes (Y)'	System	25 Aug 2020 23:05:10
	System	25 Aug 2020 23:05:10

US3312212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:02:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-25T18:04:48', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '8e4d13f4-b45e-4462-93cc-e031bb19267c' User entered '97.8'	System	25 Aug 2020 23:05:10
	System	25 Aug 2020 23:05:10

US3312212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-25T18:04:55', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '8e4d13f4-b45e-4462-93cc-e031bb19267c'	System	25 Aug 2020 23:05:10
User entered 'No (N)'	System	25 Aug 2020 23:05:10

US3312212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:02:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-25T18:05:05', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '8e4d13f4-b45e-4462-93cc-e031bb19267c' User entered '25 Aug 2020 18:05'	System	25 Aug 2020 23:05:10
	System	25 Aug 2020 23:05:10

US3312212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:02:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
User entered '25 Aug 2020 12:00'	System	21 Aug 2020 18:40:36

US3312212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:02:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
User entered '26 Aug 2020 11:59'	System	21 Aug 2020 18:40:36

US3312212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
Data entry locked.	System	21 Aug 2020 18:40:36
User entered 'Day 6'	System	21 Aug 2020 18:40:36

US3312212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:02:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-26T21:30:02', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'd1f713a4-7d16-4f96-8203-ed7d4280a1c2'	System	27 Aug 2020 02:30:53
User entered 'Yes (Y)'	System	27 Aug 2020 02:30:53

US3312212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:02:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-26T21:30:36', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'd1f713a4-7d16-4f96-8203-ed7d4280a1c2'	System	27 Aug 2020 02:30:53
User entered '97.6'	System	27 Aug 2020 02:30:53

US3312212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-26T21:30:42', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'd1f713a4-7d16-4f96-8203-ed7d4280a1c2'	System	27 Aug 2020 02:30:53
User entered 'No (N)'	System	27 Aug 2020 02:30:53

US3312212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:02:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-26T21:30:52', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'd1f713a4-7d16-4f96-8203-ed7d4280a1c2'	System	27 Aug 2020 02:30:53
User entered '26 Aug 2020 21:30'	System	27 Aug 2020 02:30:53

US3312212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:02:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
User entered '26 Aug 2020 12:00'	System	21 Aug 2020 18:40:36

US3312212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:02:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
User entered '27 Aug 2020 11:59'	System	21 Aug 2020 18:40:36

US3312212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
Data entry locked.	System	21 Aug 2020 18:40:36
User entered 'Day 7'	System	21 Aug 2020 18:40:36

US3312212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:02:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-27T19:20:05', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '8bc8a31a-25a9-42b0-8b28-82334d5fbea8' User entered 'Yes (Y)'	System	28 Aug 2020 00:20:33
	System	28 Aug 2020 00:20:33

US3312212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:02:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-27T19:20:16', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '8bc8a31a-25a9-42b0-8b28-82334d5fbea8' User entered '98.3'	System	28 Aug 2020 00:20:33
	System	28 Aug 2020 00:20:33

US3312212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-27T19:20:20', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '8bc8a31a-25a9-42b0-8b28-82334d5fbea8'	System	28 Aug 2020 00:20:33
User entered 'No (N)'	System	28 Aug 2020 00:20:33

US3312212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:02:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-27T19:20:32', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '8bc8a31a-25a9-42b0-8b28-82334d5fbea8' User entered '27 Aug 2020 19:20'	System	28 Aug 2020 00:20:33
	System	28 Aug 2020 00:20:33

US3312212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:02:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
User entered '27 Aug 2020 12:00'	System	21 Aug 2020 18:40:36

US3312212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:02:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
User entered '28 Aug 2020 11:59'	System	21 Aug 2020 18:40:36

US3312212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
Data entry locked.	System	21 Aug 2020 18:40:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 18:40:36

US3312212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:02:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-21T14:10:22', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'e4db287c-7ec5-4521-a22b-f8759d65f885'	System	21 Aug 2020 19:11:04
User entered 'None (1)'	System	21 Aug 2020 19:11:04

US3312212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:02:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-21T14:10:33', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'e4db287c-7ec5-4521-a22b-f8759d65f885'	System	21 Aug 2020 19:11:04
User entered 'No (N)'	System	21 Aug 2020 19:11:04

US3312212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-21T14:10:45', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'e4db287c-7ec5-4521-a22b-f8759d65f885' User entered 'No (N)'	System	21 Aug 2020 19:11:04
	System	21 Aug 2020 19:11:04

US3312212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:02:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-21T14:10:53', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'e4db287c-7ec5-4521-a22b-f8759d65f885'	System	21 Aug 2020 19:11:04
User entered 'None (1)'	System	21 Aug 2020 19:11:04

US3312212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:02:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-21T14:11:02', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'e4db287c-7ec5-4521-a22b-f8759d65f885'	System	21 Aug 2020 19:11:04
User entered '21 Aug 2020 14:11'	System	21 Aug 2020 19:11:04

US3312212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:02:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
User entered '21 Aug 2020 13:50'	System	21 Aug 2020 18:40:36

US3312212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:02:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
User entered '21 Aug 2020 16:20'	System	21 Aug 2020 18:40:36

US3312212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
Data entry locked.	System	21 Aug 2020 18:40:36
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 18:40:36

US3312212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:02:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-21T19:26:23', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '1ea248d0-b5ce-4f6d-b36a-302c830fa91f' User entered 'None (1)'	System	22 Aug 2020 00:28:01
	System	22 Aug 2020 00:28:01

US3312212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:02:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-21T19:27:04', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '1ea248d0-b5ce-4f6d-b36a-302c830fa91f' User entered 'No (N)'	System	22 Aug 2020 00:28:01
	System	22 Aug 2020 00:28:01

US3312212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-21T19:27:13', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '1ea248d0-b5ce-4f6d-b36a-302c830fa91f' User entered 'No (N)'	System	22 Aug 2020 00:28:01
	System	22 Aug 2020 00:28:01

US3312212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:02:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-21T19:27:37', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '1ea248d0-b5ce-4f6d-b36a-302c830fa91f' User entered 'None (1)'	System	22 Aug 2020 00:28:01
	System	22 Aug 2020 00:28:01

US3312212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:02:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-21T19:27:59', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '1ea248d0-b5ce-4f6d-b36a-302c830fa91f' User entered '21 Aug 2020 19:27'	System	22 Aug 2020 00:28:01
	System	22 Aug 2020 00:28:01

US3312212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:02:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
User entered '21 Aug 2020 17:15'	System	21 Aug 2020 18:40:36

US3312212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:02:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 18:40:36

US3312212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
Data entry locked.	System	21 Aug 2020 18:40:36
User entered 'Day 2'	System	21 Aug 2020 18:40:36

US3312212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:02:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-22T17:43:23', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '05eef647-67b7-48d1-b2a2-48f6f07ee85c'	System	22 Aug 2020 22:59:58
User entered 'None (1)'	System	22 Aug 2020 22:59:58

US3312212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:02:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-22T17:43:30', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '05eef647-67b7-48d1-b2a2-48f6f07ee85c'	System	22 Aug 2020 22:59:58
User entered 'No (N)'	System	22 Aug 2020 22:59:58

US3312212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-22T17:43:36', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '05eef647-67b7-48d1-b2a2-48f6f07ee85c'	System	22 Aug 2020 22:59:58
User entered 'No (N)'	System	22 Aug 2020 22:59:58

US3312212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:02:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-22T17:59:19', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '05eef647-67b7-48d1-b2a2-48f6f07ee85c'	System	22 Aug 2020 22:59:58
User entered 'None (1)'	System	22 Aug 2020 22:59:58

US3312212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:02:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-22T17:59:57', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '05eef647-67b7-48d1-b2a2-48f6f07ee85c'	System	22 Aug 2020 22:59:58
User entered '22 Aug 2020 17:59'	System	22 Aug 2020 22:59:58

US3312212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:02:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 18:40:36

US3312212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:02:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 18:40:36

US3312212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
Data entry locked.	System	21 Aug 2020 18:40:36
User entered 'Day 3'	System	21 Aug 2020 18:40:36

US3312212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:02:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-23T19:15:48', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '456fb8d5-a543-41a6-abe9-69ffda980c64'	System	24 Aug 2020 00:16:22
User entered 'None (1)'	System	24 Aug 2020 00:16:22

US3312212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:02:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-23T19:15:52', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '456fb8d5-a543-41a6-abe9-69ffda980c64'	System	24 Aug 2020 00:16:22
User entered 'No (N)'	System	24 Aug 2020 00:16:22

US3312212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-23T19:15:58', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '456fb8d5-a543-41a6-abe9-69ffda980c64'	System	24 Aug 2020 00:16:22
User entered 'No (N)'	System	24 Aug 2020 00:16:22

US3312212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:02:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-23T19:16:08', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '456fb8d5-a543-41a6-abe9-69ffda980c64'	System	24 Aug 2020 00:16:22
User entered 'None (1)'	System	24 Aug 2020 00:16:22

US3312212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:02:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-23T19:16:18', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '456fb8d5-a543-41a6-abe9-69ffda980c64'	System	24 Aug 2020 00:16:22
User entered '23 Aug 2020 19:16'	System	24 Aug 2020 00:16:22

US3312212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:02:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 18:40:36

US3312212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:02:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 18:40:36

US3312212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
Data entry locked.	System	21 Aug 2020 18:40:36
User entered 'Day 4'	System	21 Aug 2020 18:40:36

US3312212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:02:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-24T21:03:13', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'cceb6541-f5bc-4ef2-a2a2-28530f0561c8' User entered 'None (1)'	System	25 Aug 2020 02:04:07
	System	25 Aug 2020 02:04:07

US3312212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:02:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-24T21:03:17', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'cceb6541-f5bc-4ef2-a2a2-28530f0561c8' User entered 'No (N)'	System	25 Aug 2020 02:04:07
	System	25 Aug 2020 02:04:07

US3312212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-24T21:03:22', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'cceb6541-f5bc-4ef2-a2a2-28530f0561c8'	System	25 Aug 2020 02:04:07
User entered 'No (N)'	System	25 Aug 2020 02:04:07

US3312212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:02:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-24T21:03:55', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'cceb6541-f5bc-4ef2-a2a2-28530f0561c8' User entered 'None (1)'	System	25 Aug 2020 02:04:07
	System	25 Aug 2020 02:04:07

US3312212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:02:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-24T21:04:02', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'cceb6541-f5bc-4ef2-a2a2-28530f0561c8' User entered '24 Aug 2020 21:04'	System	25 Aug 2020 02:04:07
	System	25 Aug 2020 02:04:07

US3312212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:02:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
User entered '24 Aug 2020 12:00'	System	21 Aug 2020 18:40:36

US3312212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:02:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
User entered '25 Aug 2020 11:59'	System	21 Aug 2020 18:40:36

US3312212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
Data entry locked.	System	21 Aug 2020 18:40:36
User entered 'Day 5'	System	21 Aug 2020 18:40:36

US3312212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:02:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-25T18:05:14', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '8af27586-9ea2-4123-9710-6009e1f71fab'	System	25 Aug 2020 23:05:42
User entered 'None (1)'	System	25 Aug 2020 23:05:42

US3312212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:02:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-25T18:05:19', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '8af27586-9ea2-4123-9710-6009e1f71fab'	System	25 Aug 2020 23:05:42
User entered 'No (N)'	System	25 Aug 2020 23:05:42

US3312212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-25T18:05:24', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '8af27586-9ea2-4123-9710-6009e1f71fab'	System	25 Aug 2020 23:05:42
User entered 'No (N)'	System	25 Aug 2020 23:05:42

US3312212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:02:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-25T18:05:30', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '8af27586-9ea2-4123-9710-6009e1f71fab'	System	25 Aug 2020 23:05:42
User entered 'None (1)'	System	25 Aug 2020 23:05:42

US3312212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:02:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-25T18:05:40', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '8af27586-9ea2-4123-9710-6009e1f71fab' User entered '25 Aug 2020 18:05'	System	25 Aug 2020 23:05:42
	System	25 Aug 2020 23:05:42

US3312212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:02:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
User entered '25 Aug 2020 12:00'	System	21 Aug 2020 18:40:36

US3312212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:02:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
User entered '26 Aug 2020 11:59'	System	21 Aug 2020 18:40:36

US3312212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
Data entry locked.	System	21 Aug 2020 18:40:36
User entered 'Day 6'	System	21 Aug 2020 18:40:36

US3312212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:02:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-26T21:31:01', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '7e3958b4-096b-41cc-b7b8-c8ff34bcbcd0'	System	27 Aug 2020 02:31:37
User entered 'None (1)'	System	27 Aug 2020 02:31:37

US3312212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:02:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-26T21:31:11', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '7e3958b4-096b-41cc-b7b8-c8ff34bcbcd0'	System	27 Aug 2020 02:31:37
User entered 'No (N)'	System	27 Aug 2020 02:31:37

US3312212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-26T21:31:18', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '7e3958b4-096b-41cc-b7b8-c8ff34bcbcd0' User entered 'No (N)'	System	27 Aug 2020 02:31:37
	System	27 Aug 2020 02:31:37

US3312212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:02:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-26T21:31:27', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '7e3958b4-096b-41cc-b7b8-c8ff34bcbcd0'	System	27 Aug 2020 02:31:37
User entered 'None (1)'	System	27 Aug 2020 02:31:37

US3312212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:02:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-26T21:31:34', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '7e3958b4-096b-41cc-b7b8-c8ff34bcbcd0' User entered '26 Aug 2020 21:31'	System	27 Aug 2020 02:31:37
	System	27 Aug 2020 02:31:37

US3312212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:02:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
User entered '26 Aug 2020 12:00'	System	21 Aug 2020 18:40:36

US3312212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:02:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
User entered '27 Aug 2020 11:59'	System	21 Aug 2020 18:40:36

US3312212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
Data entry locked.	System	21 Aug 2020 18:40:36
User entered 'Day 7'	System	21 Aug 2020 18:40:36

US3312212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:02:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-27T19:20:40', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'b507cf68-493d-416a-b584-d6be731f02d5'	System	28 Aug 2020 00:21:08
User entered 'None (1)'	System	28 Aug 2020 00:21:08

US3312212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:02:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-27T19:20:45', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'b507cf68-493d-416a-b584-d6be731f02d5'	System	28 Aug 2020 00:21:08
User entered 'No (N)'	System	28 Aug 2020 00:21:08

US3312212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-27T19:20:51', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'b507cf68-493d-416a-b584-d6be731f02d5'	System	28 Aug 2020 00:21:08
User entered 'No (N)'	System	28 Aug 2020 00:21:08

US3312212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:02:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-27T19:20:57', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'b507cf68-493d-416a-b584-d6be731f02d5'	System	28 Aug 2020 00:21:08
User entered 'None (1)'	System	28 Aug 2020 00:21:08

US3312212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:02:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-27T19:21:05', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'b507cf68-493d-416a-b584-d6be731f02d5' User entered '27 Aug 2020 19:21'	System	28 Aug 2020 00:21:08
	System	28 Aug 2020 00:21:08

US3312212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:02:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
User entered '27 Aug 2020 12:00'	System	21 Aug 2020 18:40:36

US3312212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:02:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
User entered '28 Aug 2020 11:59'	System	21 Aug 2020 18:40:36

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
Data entry locked.	System	21 Aug 2020 18:40:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 18:40:36

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:15

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-21T14:11:15', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'a374fe5d-cbc8-4f54-a66e-8615fa147fff'	System	21 Aug 2020 19:12:38
User entered 'None (0)'	System	21 Aug 2020 19:12:38

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:15

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-21T14:11:34', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'a374fe5d-cbc8-4f54-a66e-8615fa147fff'	System	21 Aug 2020 19:12:38
User entered 'None (0)'	System	21 Aug 2020 19:12:38

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-21T14:11:41', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'a374fe5d-cbc8-4f54-a66e-8615fa147fff'	System	21 Aug 2020 19:12:38
User entered 'None (0)'	System	21 Aug 2020 19:12:38

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-21T14:11:56', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'a374fe5d-cbc8-4f54-a66e-8615fa147fff' User entered 'None (0)'	System	21 Aug 2020 19:12:38
	System	21 Aug 2020 19:12:38

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-21T14:12:03', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'a374fe5d-cbc8-4f54-a66e-8615fa147fff'	System	21 Aug 2020 19:12:38
User entered 'None (0)'	System	21 Aug 2020 19:12:38

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:15

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-21T14:12:12', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'a374fe5d-cbc8-4f54-a66e-8615fa147fff'	System	21 Aug 2020 19:12:38
User entered 'None (0)'	System	21 Aug 2020 19:12:38

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-21T14:12:22', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'a374fe5d-cbc8-4f54-a66e-8615fa147fff'	System	21 Aug 2020 19:12:38
User entered 'No (N)'	System	21 Aug 2020 19:12:38

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-21T14:12:36', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'a374fe5d-cbc8-4f54-a66e-8615fa147fff'	System	21 Aug 2020 19:12:38
User entered '21 Aug 2020 14:12'	System	21 Aug 2020 19:12:38

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
User entered '21 Aug 2020 13:50'	System	21 Aug 2020 18:40:36

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:02:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
User entered '21 Aug 2020 16:20'	System	21 Aug 2020 18:40:36

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
Data entry locked.	System	21 Aug 2020 18:40:36
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 18:40:36

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:15

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-21T19:28:09', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'a57167cc-8530-4961-905b-df0267605bb9' User entered 'None (0)'	System	22 Aug 2020 00:29:14
	System	22 Aug 2020 00:29:14

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:15

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-21T19:28:16', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'a57167cc-8530-4961-905b-df0267605bb9' User entered 'None (0)'	System	22 Aug 2020 00:29:14
	System	22 Aug 2020 00:29:14

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-21T19:28:20', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'a57167cc-8530-4961-905b-df0267605bb9' User entered 'None (0)'	System	22 Aug 2020 00:29:14
	System	22 Aug 2020 00:29:14

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-21T19:28:31', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'a57167cc-8530-4961-905b-df0267605bb9' User entered 'None (0)'	System	22 Aug 2020 00:29:14
	System	22 Aug 2020 00:29:14

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-21T19:28:40', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'a57167cc-8530-4961-905b-df0267605bb9' User entered 'None (0)'	System	22 Aug 2020 00:29:14
	System	22 Aug 2020 00:29:14

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:15

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-21T19:28:46', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'a57167cc-8530-4961-905b-df0267605bb9' User entered 'None (0)'	System	22 Aug 2020 00:29:14
	System	22 Aug 2020 00:29:14

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-21T19:28:55', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'a57167cc-8530-4961-905b-df0267605bb9' User entered 'No (N)'	System	22 Aug 2020 00:29:14
	System	22 Aug 2020 00:29:14

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-21T19:29:10', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'a57167cc-8530-4961-905b-df0267605bb9' User entered '21 Aug 2020 19:29'	System	22 Aug 2020 00:29:14
	System	22 Aug 2020 00:29:14

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
User entered '21 Aug 2020 17:15'	System	21 Aug 2020 18:40:36

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:02:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 18:40:36

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
Data entry locked.	System	21 Aug 2020 18:40:36
User entered 'Day 2'	System	21 Aug 2020 18:40:36

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:15

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-22T18:00:10', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '2dc943fa-e79f-410a-9d18-6919413befa6'	System	22 Aug 2020 23:01:32
User entered 'None (0)'	System	22 Aug 2020 23:01:32

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:15

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-22T18:00:17', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '2dc943fa-e79f-410a-9d18-6919413befa6'	System	22 Aug 2020 23:01:32
User entered 'None (0)'	System	22 Aug 2020 23:01:32

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-22T18:00:40', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '2dc943fa-e79f-410a-9d18-6919413befa6' User entered 'None (0)'	System	22 Aug 2020 23:01:32
	System	22 Aug 2020 23:01:32

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-22T18:00:46', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '2dc943fa-e79f-410a-9d18-6919413befa6' User entered 'None (0)'	System	22 Aug 2020 23:01:32
	System	22 Aug 2020 23:01:32

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-22T18:00:52', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '2dc943fa-e79f-410a-9d18-6919413befa6'	System	22 Aug 2020 23:01:32
User entered 'None (0)'	System	22 Aug 2020 23:01:32

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:15

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-22T18:01:03', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '2dc943fa-e79f-410a-9d18-6919413befa6'	System	22 Aug 2020 23:01:32
User entered 'None (0)'	System	22 Aug 2020 23:01:32

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-22T18:01:11', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '2dc943fa-e79f-410a-9d18-6919413befa6'	System	22 Aug 2020 23:01:32
User entered 'No (N)'	System	22 Aug 2020 23:01:32

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-22T18:01:29', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '2dc943fa-e79f-410a-9d18-6919413befa6'	System	22 Aug 2020 23:01:32
User entered '22 Aug 2020 18:01'	System	22 Aug 2020 23:01:32

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 18:40:36

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:02:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 18:40:36

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
Data entry locked.	System	21 Aug 2020 18:40:36
User entered 'Day 3'	System	21 Aug 2020 18:40:36

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:15

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-23T19:16:25', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '0990fb41-aa5e-4490-866e-88bb164d2b71' User entered 'None (0)'	System	24 Aug 2020 00:17:05
	System	24 Aug 2020 00:17:05

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:15

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-23T19:16:29', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '0990fb41-aa5e-4490-866e-88bb164d2b71' User entered 'None (0)'	System	24 Aug 2020 00:17:05
	System	24 Aug 2020 00:17:05

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-23T19:16:33', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '0990fb41-aa5e-4490-866e-88bb164d2b71' User entered 'None (0)'	System	24 Aug 2020 00:17:05
	System	24 Aug 2020 00:17:05

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-23T19:16:38', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '0990fb41-aa5e-4490-866e-88bb164d2b71' User entered 'None (0)'	System	24 Aug 2020 00:17:05
	System	24 Aug 2020 00:17:05

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-23T19:16:41', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '0990fb41-aa5e-4490-866e-88bb164d2b71' User entered 'None (0)'	System	24 Aug 2020 00:17:05
	System	24 Aug 2020 00:17:05

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:15

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-23T19:16:45', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '0990fb41-aa5e-4490-866e-88bb164d2b71' User entered 'None (0)'	System	24 Aug 2020 00:17:05
	System	24 Aug 2020 00:17:05

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-23T19:16:51', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '0990fb41-aa5e-4490-866e-88bb164d2b71'	System	24 Aug 2020 00:17:05
User entered 'No (N)'	System	24 Aug 2020 00:17:05

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-23T19:17:01', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '0990fb41-aa5e-4490-866e-88bb164d2b71' User entered '23 Aug 2020 19:17'	System	24 Aug 2020 00:17:05
	System	24 Aug 2020 00:17:05

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 18:40:36

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:02:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 18:40:36

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
Data entry locked.	System	21 Aug 2020 18:40:36
User entered 'Day 4'	System	21 Aug 2020 18:40:36

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:15

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-24T21:04:09', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '2fca779f-b131-42ea-829d-13ac094cfa0d' User entered 'None (0)'	System	25 Aug 2020 02:05:11
	System	25 Aug 2020 02:05:11

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:15

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-24T21:04:26', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '2fca779f-b131-42ea-829d-13ac094cfa0d'	System	25 Aug 2020 02:05:11
User entered 'No interference with activity (1)'	System	25 Aug 2020 02:05:11

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-24T21:04:30', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '2fca779f-b131-42ea-829d-13ac094cfa0d' User entered 'None (0)'	System	25 Aug 2020 02:05:11
	System	25 Aug 2020 02:05:11

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-24T21:04:34', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '2fca779f-b131-42ea-829d-13ac094cfa0d' User entered 'None (0)'	System	25 Aug 2020 02:05:11
	System	25 Aug 2020 02:05:11

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-24T21:04:38', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '2fca779f-b131-42ea-829d-13ac094cfa0d' User entered 'None (0)'	System	25 Aug 2020 02:05:11
	System	25 Aug 2020 02:05:11

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:15

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-24T21:04:41', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '2fca779f-b131-42ea-829d-13ac094cfa0d' User entered 'None (0)'	System	25 Aug 2020 02:05:11
	System	25 Aug 2020 02:05:11

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-24T21:04:56', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '2fca779f-b131-42ea-829d-13ac094cfa0d' User entered 'No (N)'	System	25 Aug 2020 02:05:11
	System	25 Aug 2020 02:05:11

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-24T21:05:10', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '2fca779f-b131-42ea-829d-13ac094cfa0d' User entered '24 Aug 2020 21:05'	System	25 Aug 2020 02:05:11
	System	25 Aug 2020 02:05:11

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
User entered '24 Aug 2020 12:00'	System	21 Aug 2020 18:40:36

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:02:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
User entered '25 Aug 2020 11:59'	System	21 Aug 2020 18:40:36

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
Data entry locked.	System	21 Aug 2020 18:40:36
User entered 'Day 5'	System	21 Aug 2020 18:40:36

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:15

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-25T18:05:47', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '2dd3aa12-5ed4-4579-a0d9-96e71cfde8e2' User entered 'None (0)'	System	25 Aug 2020 23:06:43
	System	25 Aug 2020 23:06:43

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:15

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-25T18:05:56', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '2dd3aa12-5ed4-4579-a0d9-96e71cfde8e2' User entered 'None (0)'	System	25 Aug 2020 23:06:43
	System	25 Aug 2020 23:06:43

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-25T18:06:02', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '2dd3aa12-5ed4-4579-a0d9-96e71cfde8e2' User entered 'None (0)'	System	25 Aug 2020 23:06:43
	System	25 Aug 2020 23:06:43

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-25T18:06:10', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '2dd3aa12-5ed4-4579-a0d9-96e71cfde8e2' User entered 'None (0)'	System	25 Aug 2020 23:06:43
	System	25 Aug 2020 23:06:43

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-25T18:06:14', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '2dd3aa12-5ed4-4579-a0d9-96e71cfde8e2' User entered 'None (0)'	System	25 Aug 2020 23:06:43
	System	25 Aug 2020 23:06:43

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:15

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-25T18:06:18', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '2dd3aa12-5ed4-4579-a0d9-96e71cfde8e2' User entered 'None (0)'	System	25 Aug 2020 23:06:43
	System	25 Aug 2020 23:06:43

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-25T18:06:25', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '2dd3aa12-5ed4-4579-a0d9-96e71cfde8e2'	System	25 Aug 2020 23:06:43
User entered 'No (N)'	System	25 Aug 2020 23:06:43

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-25T18:06:39', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '2dd3aa12-5ed4-4579-a0d9-96e71cfde8e2' User entered '25 Aug 2020 18:06'	System	25 Aug 2020 23:06:43
	System	25 Aug 2020 23:06:43

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
User entered '25 Aug 2020 12:00'	System	21 Aug 2020 18:40:36

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:02:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
User entered '26 Aug 2020 11:59'	System	21 Aug 2020 18:40:36

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
Data entry locked.	System	21 Aug 2020 18:40:36
User entered 'Day 6'	System	21 Aug 2020 18:40:36

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:15

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-26T21:31:46', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'ec296b31-1514-4899-a1c1-1572cd032724' User entered 'None (0)'	System	27 Aug 2020 02:32:43
	System	27 Aug 2020 02:32:43

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:15

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-26T21:32:05', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'ec296b31-1514-4899-a1c1-1572cd032724'	System	27 Aug 2020 02:32:43
User entered 'No interference with activity (1)'	System	27 Aug 2020 02:32:43

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-26T21:32:12', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'ec296b31-1514-4899-a1c1-1572cd032724' User entered 'None (0)'	System	27 Aug 2020 02:32:43
	System	27 Aug 2020 02:32:43

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-26T21:32:16', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'ec296b31-1514-4899-a1c1-1572cd032724' User entered 'None (0)'	System	27 Aug 2020 02:32:43
	System	27 Aug 2020 02:32:43

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-26T21:32:20', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'ec296b31-1514-4899-a1c1-1572cd032724' User entered 'None (0)'	System	27 Aug 2020 02:32:43
	System	27 Aug 2020 02:32:43

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:15

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-26T21:32:24', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'ec296b31-1514-4899-a1c1-1572cd032724' User entered 'None (0)'	System	27 Aug 2020 02:32:43
	System	27 Aug 2020 02:32:43

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-26T21:32:31', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'ec296b31-1514-4899-a1c1-1572cd032724'	System	27 Aug 2020 02:32:43
User entered 'No (N)'	System	27 Aug 2020 02:32:43

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-26T21:32:40', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'ec296b31-1514-4899-a1c1-1572cd032724'	System	27 Aug 2020 02:32:43
User entered '26 Aug 2020 21:32'	System	27 Aug 2020 02:32:43

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
User entered '26 Aug 2020 12:00'	System	21 Aug 2020 18:40:36

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:02:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
User entered '27 Aug 2020 11:59'	System	21 Aug 2020 18:40:36

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
Data entry locked.	System	21 Aug 2020 18:40:36
User entered 'Day 7'	System	21 Aug 2020 18:40:36

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:15

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-27T19:21:14', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'b74ab465-4c66-4e9e-8f54-db8a599194b6' User entered 'None (0)'	System	28 Aug 2020 00:21:53
	System	28 Aug 2020 00:21:53

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:15

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-27T19:21:19', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'b74ab465-4c66-4e9e-8f54-db8a599194b6' User entered 'None (0)'	System	28 Aug 2020 00:21:53
	System	28 Aug 2020 00:21:53

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-27T19:21:25', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'b74ab465-4c66-4e9e-8f54-db8a599194b6' User entered 'None (0)'	System	28 Aug 2020 00:21:53
	System	28 Aug 2020 00:21:53

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-27T19:21:29', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'b74ab465-4c66-4e9e-8f54-db8a599194b6' User entered 'None (0)'	System	28 Aug 2020 00:21:53
	System	28 Aug 2020 00:21:53

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-27T19:21:34', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'b74ab465-4c66-4e9e-8f54-db8a599194b6' User entered 'None (0)'	System	28 Aug 2020 00:21:53
	System	28 Aug 2020 00:21:53

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:15

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-27T19:21:43', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'b74ab465-4c66-4e9e-8f54-db8a599194b6' User entered 'None (0)'	System	28 Aug 2020 00:21:53
	System	28 Aug 2020 00:21:53

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-27T19:21:48', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'b74ab465-4c66-4e9e-8f54-db8a599194b6' User entered 'No (N)'	System	28 Aug 2020 00:21:53
	System	28 Aug 2020 00:21:53

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-08-27T19:21:52', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'b74ab465-4c66-4e9e-8f54-db8a599194b6' User entered '27 Aug 2020 19:21'	System	28 Aug 2020 00:21:53
	System	28 Aug 2020 00:21:53

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
User entered '27 Aug 2020 12:00'	System	21 Aug 2020 18:40:36

US3312212

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:02:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:25:07
User entered '28 Aug 2020 11:59'	System	21 Aug 2020 18:40:36

US3312212

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:16
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 19:38:30

US3312212

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:16
User entered '28 Aug 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 19:38:30

US3312212

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:16
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 19:38:30

US3312212

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:15

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:16
User entered empty.	(b) (4)	28 Aug 2020 19:38:30
	Karol Moore (b) (4)	
	(b) (4)	

US3312212

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:16
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	28 Aug 2020 19:38:57

US3312212

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User entered 'I'	System	28 Aug 2020 19:38:57

US3312212

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Sep 2020 00:42:58

US3312212

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:16
User entered '04 Sep 2020'	(b) (4) (b) (4), (b) (6)	05 Sep 2020 00:42:58

US3312212

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:16
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	05 Sep 2020 00:42:58

US3312212

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:15

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Sep 2020 00:42:58

US3312212

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Sep 2020 00:43:03

US3312212

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 11:32:15
User entered 'I'	System	05 Sep 2020 00:43:03

US3312212

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:14
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 13:47:44

US3312212

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:15

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:14
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:16
User closed query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	18 Sep 2020 06:49:45
Query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.'	(b) (4), (b) (6)	17 Sep 2020 13:58:00
answered with 'Correct as entered. Protocol deviation noted for out of window' (Site from System).		
User opened query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	17 Sep 2020 13:47:44
User entered '16 Sep 2020'	(b) (4), (b) (6)	17 Sep 2020 13:47:44

US3312212

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:14
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:16
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 13:47:44

US3312212

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:15

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:14
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:16
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 13:47:44

US3312212

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:14
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 13:58:06

US3312212

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:14
User entered 'I'	System	17 Sep 2020 13:58:06

US3312212

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:02:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 01:22:00

US3312212

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:02:15

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 15OCT2020 is reported under Visit 3 Day 57 visit in PPD central lab, however Immunogenicity Assessment form is not completed in EDC. Please complete, else clarify. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:25:05
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 15OCT2020 is reported under Visit 3 Day 57 visit in PPD central lab, however Immunogenicity Assessment form is not completed in EDC. Please complete, else clarify. Thank you. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 22:42:28
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 15OCT2020 is reported under Visit 3 Day 57 visit in PPD central lab, however Immunogenicity Assessment form is not completed in EDC. Please complete, else clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 10:51:11
User entered '18 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 01:22:00

US3312212

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:02:15

[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 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 01:22:00

US3312212

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:02:15

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User entered 'VISIT2'	System	25 Sep 2020 01:22:00

US3312212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:15

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	25 Sep 2020 01:22:49

US3312212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 01:22:49

US3312212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '18 Sep 2020'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 01:22:49

US3312212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:15

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '09:05'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 01:22:49

US3312212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:15

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User entered '18 Sep 2020 09:05'	System	25 Sep 2020 01:22:49

US3312212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:15

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '98.5' F	(b) (4) (b) (4), (b) (6)	25 Sep 2020 01:22:49

US3312212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 01:22:49

US3312212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 01:22:49

US3312212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '73'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 01:22:49

US3312212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User entered 'bpm'	System	25 Sep 2020 01:22:49

US3312212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '16'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 01:22:49

US3312212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User entered 'breaths/min'	System	25 Sep 2020 01:22:49

US3312212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '108'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 01:22:49

US3312212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User entered 'mmHg'	System	25 Sep 2020 01:22:49

US3312212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User closed query 'Per CDM: Thank you for your response. However, please indicate if PI considers diastolic blood pressure NCS or CS and record AE if applicable. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Oct 2020 12:00:36
Query 'Per CDM: Thank you for your response. However, please indicate if PI considers diastolic blood pressure NCS or CS and record AE if applicable. Thank you' answered with 'Correct as entered NCS. Not an AE. Per protocol toxicity table, diastolic blood pressure not defined.' (Site from DM).	Heather Barker (b) (4) (b) (4)	21 Oct 2020 20:03:19
User opened query 'Per CDM: Thank you for your response. However, please indicate if PI considers diastolic blood pressure NCS or CS and record AE if applicable. Thank you' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 18:33:40
User closed query 'Per CDM: Please indicate if diastolic blood pressure is NCS or CS and report AE if necessary. Thank you.' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 18:33:07
Query 'Per CDM: Please indicate if diastolic blood pressure is NCS or CS and report AE if necessary. Thank you.' answered with 'CORRECT AS ENTERED. PER PROTOCOL TOXICITY TABLE DIASTOLIC BLOOD PRESSURE IS NOT DEFINED' (Site from DM).	Karol Moore (b) (4) (b) (4)	07 Oct 2020 00:26:58
User opened query 'Per CDM: Please indicate if diastolic blood pressure is NCS or CS and report AE if necessary. Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 13:10:58
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	25 Sep 2020 13:10:44
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 'NA' (Site from System).	(b) (4), (b) (6)	25 Sep 2020 01:23:01

US3312212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
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). User entered '50'	(b) (4), (b) (6)	25 Sep 2020 01:22:49

US3312212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:15

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User entered 'mmHg'	System	25 Sep 2020 01:22:49

US3312212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:15

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	25 Sep 2020 01:22:49

US3312212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 01:22:49

US3312212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 01:22:49

US3312212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:15

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 01:22:49

US3312212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:15

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User entered empty.	System	25 Sep 2020 01:22:49

US3312212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 01:22:49

US3312212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 01:22:49

US3312212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 01:22:49

US3312212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 01:22:49

US3312212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User entered empty.	System	25 Sep 2020 01:22:49

US3312212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 01:22:49

US3312212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User entered empty.	System	25 Sep 2020 01:22:49

US3312212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 01:22:49

US3312212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User entered empty.	System	25 Sep 2020 01:22:49

US3312212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 01:22:49

US3312212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:15

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User entered empty.	System	25 Sep 2020 01:22:49

US3312212

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:02:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 01:23:11

US3312212

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:02:15

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '18 Sep 2020'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 01:23:11

US3312212

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:15

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 01:23:29

US3312212

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:15

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'Physician withheld dose due to Adverse Event (PHYSICIAN AE)'	(b) (4), (b) (6)	25 Sep 2020 01:23:29

US3312212

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:15

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 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 01:23:29

US3312212

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:15

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User entered empty.	System	25 Sep 2020 01:23:29

US3312212

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:15

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 01:23:29

US3312212

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:15

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 01:23:29

US3312212

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:15

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User entered empty.	System	25 Sep 2020 01:23:29

US3312212

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:15

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 01:23:29

US3312212

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:15

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User entered empty.	System	25 Sep 2020 01:23:29

US3312212

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:15

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User entered empty.	System	25 Sep 2020 01:23:29

US3312212

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 01:23:50

US3312212

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:15

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '18 Sep 2020'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 01:23:50

US3312212

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:15

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '09:44'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 01:23:50

US3312212

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:15

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User entered '18 Sep 2020 09:44'	System	25 Sep 2020 01:23:50

US3312212

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:02:15

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '18 Sep 2020'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 01:24:07

US3312212

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:02:15

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	25 Sep 2020 01:24:07

US3312212

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:02:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 01:24:07

US3312212

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:02:15

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '09:36'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 01:24:07

US3312212

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:02:15

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User entered '18 Sep 2020 09:36'	System	25 Sep 2020 01:24:07

US3312212

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:02:15

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	25 Sep 2020 01:24:07

US3312212

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:02:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 01:24:07

US3312212

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:02:15

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 01:24:07

US3312212

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:02:15

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User entered empty.	System	25 Sep 2020 01:24:07

US3312212

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 01:24:13

US3312212

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User entered 'I'	System	25 Sep 2020 01:24:13

US3312212

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:16
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	07 Oct 2020 00:33:03

US3312212

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:16
User entered '25 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	07 Oct 2020 00:33:03

US3312212

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:16
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karol Moore (b) (4) (b) (4)	07 Oct 2020 00:33:03

US3312212

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:15

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:16
User entered empty.	(b) (4)	07 Oct 2020 00:33:03
	Karol Moore (b) (4)	
	(b) (4)	

US3312212

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:16
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	07 Oct 2020 00:33:12

US3312212

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User entered 'I'	System	07 Oct 2020 00:33:12

US3312212

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:16
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	08 Oct 2020 12:50:07

US3312212

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:16
User entered '01 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	08 Oct 2020 12:50:07

US3312212

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:16
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karol Moore (b) (4) (b) (4)	08 Oct 2020 12:50:07

US3312212

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:15

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:16
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	08 Oct 2020 12:50:07

US3312212

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:16
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	08 Oct 2020 12:50:11

US3312212

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User entered 'I'	System	08 Oct 2020 12:50:11

US3312212

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:16
User entered 'Yes (Y)'	(b) (4) Monica Atwood (b) (4)	12 Oct 2020 15:30:38

US3312212

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:15

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:16
User entered '9 Oct 2020'	(b) (4) Monica Atwood (b) (4)	12 Oct 2020 15:30:38

US3312212

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:16
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Monica Atwood (b) (4)	12 Oct 2020 15:30:38

US3312212

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:15

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:16
User entered empty.	(b) (4) Monica Atwood (b) (4)	12 Oct 2020 15:30:38

US3312212

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:16
User entered 'Yes (Y)'	(b) (4) Monica Atwood (b) (4)	12 Oct 2020 15:30:42

US3312212

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User entered 'I'	System	12 Oct 2020 15:30:42

US3312212

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:02:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:07:27

US3312212

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '15 Oct 2020'	(b) (4) Karol Moore (b) (4)	10 Nov 2020 14:07:27

US3312212

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:02:15

[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 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'Clinic (Clinic)'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:07:27

US3312212

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:02:15

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User entered 'VISIT3'	System	10 Nov 2020 14:07:27

US3312212

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:07:53

US3312212

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '15 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:07:53

US3312212

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:15

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '09:28'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:07:53

US3312212

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:15

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User entered '15 Oct 2020 09:28'	System	10 Nov 2020 14:07:53

US3312212

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '98.2' F	(b) (4) Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:07:53

US3312212

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:07:53

US3312212

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:07:53

US3312212

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '64'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:07:53

US3312212

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User entered 'bpm'	System	10 Nov 2020 14:07:53

US3312212

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '16'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:07:53

US3312212

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User entered 'breaths/min'	System	10 Nov 2020 14:07:53

US3312212

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '138'	(b) (4) Karol Moore (b) (4)	10 Nov 2020 14:07:53

US3312212

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User entered 'mmHg'	System	10 Nov 2020 14:07:53

US3312212

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '68'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:07:53

US3312212

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:15

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User entered 'mmHg'	System	10 Nov 2020 14:07:53

US3312212

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:15

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40

US3312212

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:15

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40

US3312212

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:02:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	10 Nov 2020 14:08:04

US3312212

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:02:15

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '15 Oct 2020'	(b) (4) Karol Moore (b) (4)	10 Nov 2020 14:08:04
	(b) (4)	

US3312212

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:08:20

US3312212

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:15

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '15 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:08:20

US3312212

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:15

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered '10:07'	(b) (4) Karol Moore (b) (4) (b) (4)	10 Nov 2020 14:08:20

US3312212

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:15

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User entered '15 Oct 2020 10:07'	System	10 Nov 2020 14:08:20

US3312212

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 22:09:30
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	10 Nov 2020 14:08:24

US3312212

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User entered '1'	System	10 Nov 2020 14:08:24

US3312212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:50:57
Data entry locked.	System	21 Aug 2020 18:40:36
User entered 'Day 64'	System	21 Aug 2020 18:40:36

US3312212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[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)	24 Apr 2021 05:50:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-10-23T09:14:44', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '50436846-e43b-494e-91a4-3994418607a5'	System	23 Oct 2020 14:15:24
User entered 'No (N)'	System	23 Oct 2020 14:15:24

US3312212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

Have you been exposed to someone with 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)	24 Apr 2021 05:50:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-10-23T09:14:53', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '50436846-e43b-494e-91a4-3994418607a5'	System	23 Oct 2020 14:15:24
User entered 'No (N)'	System	23 Oct 2020 14:15:24

US3312212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:50:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-10-23T09:15:22', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '50436846-e43b-494e-91a4-3994418607a5' User entered '23 Oct 2020 09:15:22'	System	23 Oct 2020 14:15:24
	System	23 Oct 2020 14:15:24

US3312212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:50:57
Data entry locked.	System	21 Aug 2020 18:40:36
User entered '21 Oct 2020 00:01'	System	21 Aug 2020 18:40:36

US3312212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:50:57
Data entry locked.	System	21 Aug 2020 18:40:36
User entered '25 Oct 2020 23:59'	System	21 Aug 2020 18:40:36

US3312212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:50:57
Data entry locked.	System	21 Aug 2020 18:40:36
User entered 'Day 71'	System	21 Aug 2020 18:40:36

US3312212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

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)	24 Apr 2021 05:50:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-10-29T15:19:07', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '4e19ae34-0167-4566-8c23-3558d92664d2'	System	29 Oct 2020 20:19:50
User entered 'No (N)'	System	29 Oct 2020 20:19:50

US3312212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

Have you been exposed to someone with 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)	24 Apr 2021 05:50:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-10-29T15:19:19', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '4e19ae34-0167-4566-8c23-3558d92664d2'	System	29 Oct 2020 20:19:50
User entered 'No (N)'	System	29 Oct 2020 20:19:50

US3312212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:50:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-10-29T15:19:44', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '4e19ae34-0167-4566-8c23-3558d92664d2' User entered '29 Oct 2020 15:19:44'	System	29 Oct 2020 20:19:50
	System	29 Oct 2020 20:19:50

US3312212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:50:57
Data entry locked.	System	21 Aug 2020 18:40:36
User entered '28 Oct 2020 00:01'	System	21 Aug 2020 18:40:36

US3312212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:50:57
Data entry locked.	System	21 Aug 2020 18:40:36
User entered '01 Nov 2020 23:59'	System	21 Aug 2020 18:40:36

US3312212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:50:57
Data entry locked.	System	21 Aug 2020 18:40:36
User entered 'Day 78'	System	21 Aug 2020 18:40:36

US3312212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[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)	24 Apr 2021 05:50:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-11-05T15:26:02', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '7744d615-1249-4b7d-8c29-af43c3d4dae0'	System	05 Nov 2020 21:27:06
User entered 'No (N)'	System	05 Nov 2020 21:27:06

US3312212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

Have you been exposed to someone with 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)	24 Apr 2021 05:50:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-11-05T15:26:14', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '7744d615-1249-4b7d-8c29-af43c3d4dae0'	System	05 Nov 2020 21:27:06
User entered 'No (N)'	System	05 Nov 2020 21:27:06

US3312212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:50:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-11-05T15:27:03', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '7744d615-1249-4b7d-8c29-af43c3d4dae0' User entered '05 Nov 2020 15:27:03'	System	05 Nov 2020 21:27:06
	System	05 Nov 2020 21:27:06

US3312212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:50:57
Data entry locked.	System	21 Aug 2020 18:40:36
User entered '04 Nov 2020 00:01'	System	21 Aug 2020 18:40:36

US3312212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:50:57
Data entry locked.	System	21 Aug 2020 18:40:36
User entered '08 Nov 2020 23:59'	System	21 Aug 2020 18:40:36

US3312212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:50:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:41:03
Data entry locked.	System	21 Aug 2020 18:40:36
User entered 'Day 92'	System	21 Aug 2020 18:40:36

US3312212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[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)	24 Apr 2021 05:50:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:41:03

US3312212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Have you been exposed to someone with 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)	24 Apr 2021 05:50:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:41:03

US3312212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Please 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)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:50:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:41:03

US3312212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[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)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:50:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:41:03

US3312212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:50:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:41:03

US3312212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:50:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:41:03

US3312212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:50:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:41:03

US3312212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:50:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:41:03

US3312212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:50:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:41:03

US3312212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:50:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:41:03

US3312212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:50:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:41:03

US3312212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:50:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:41:03

US3312212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:50:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:41:03

US3312212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:50:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:41:03

US3312212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:50:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:41:03

US3312212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:50:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:41:03

US3312212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:50:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:41:03

US3312212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:50:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:41:03

US3312212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:50:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:41:03

US3312212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:50:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:41:03

US3312212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:50:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:41:03

US3312212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Please 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)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:50:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:41:03

US3312212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[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)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:50:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:41:03

US3312212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Please 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)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:50:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:41:03

US3312212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:50:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:41:03

US3312212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:50:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:41:03
Data entry locked.	System	21 Aug 2020 18:40:36
User entered '18 Nov 2020 00:01'	System	21 Aug 2020 18:40:36

US3312212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:50:57
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:41:03
Data entry locked.	System	21 Aug 2020 18:40:36
User entered '22 Nov 2020 23:59'	System	21 Aug 2020 18:40:36

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[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 (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-11-19T21:15:36', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '935e81ca-b9a4-429f-af1a-89619015a1e5' User entered 'No (N)'	System	20 Nov 2020 03:16:15
	System	20 Nov 2020 03:16:15

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

Have you been exposed to someone with 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 (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-11-19T21:15:48', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '935e81ca-b9a4-429f-af1a-89619015a1e5' User entered 'No (N)'	System	20 Nov 2020 03:16:15
	System	20 Nov 2020 03:16:15

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-11-19T21:16:12', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '935e81ca-b9a4-429f-af1a-89619015a1e5' User entered '19 Nov 2020 21:16:12'	System	20 Nov 2020 03:16:15

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '15 Nov 2020 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '19 Nov 2020 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[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 (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-11-26T20:22:11', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '7469b08c-9b2b-4620-8f16-5858e032b786'	System	27 Nov 2020 02:22:34
User entered 'No (N)'	System	27 Nov 2020 02:22:34

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

Have you been exposed to someone with 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 (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-11-26T20:22:19', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '7469b08c-9b2b-4620-8f16-5858e032b786'	System	27 Nov 2020 02:22:34
User entered 'No (N)'	System	27 Nov 2020 02:22:34

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-11-26T20:22:32', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '7469b08c-9b2b-4620-8f16-5858e032b786' User entered '26 Nov 2020 20:22:32'	System	27 Nov 2020 02:22:34

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[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 (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-12-03T06:39:40', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'a5d36c99-68d9-441f-a6a8-b86e2e1a5706'	System	03 Dec 2020 12:40:17
User entered 'No (N)'	System	03 Dec 2020 12:40:17

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

Have you been exposed to someone with 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 (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-12-03T06:39:57', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'a5d36c99-68d9-441f-a6a8-b86e2e1a5706'	System	03 Dec 2020 12:40:17
User entered 'No (N)'	System	03 Dec 2020 12:40:17

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-12-03T06:40:13', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'a5d36c99-68d9-441f-a6a8-b86e2e1a5706' User entered '03 Dec 2020 06:40:13'	System	03 Dec 2020 12:40:17
	System	03 Dec 2020 12:40:17

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[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 (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-12-09T21:14:53', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '56e7bdca-1eef-4984-bbcd-2ec18e497b5f' User entered 'No (N)'	System	10 Dec 2020 03:15:18
	System	10 Dec 2020 03:15:18

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

Have you been exposed to someone with 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 (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-12-09T21:15:00', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '56e7bdca-1eef-4984-bbcd-2ec18e497b5f' User entered 'No (N)'	System	10 Dec 2020 03:15:18
	System	10 Dec 2020 03:15:18

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-12-09T21:15:17', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '56e7bdca-1eef-4984-bbcd-2ec18e497b5f' User entered '09 Dec 2020 21:15:17'	System	10 Dec 2020 03:15:18
	System	10 Dec 2020 03:15:18

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[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 (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-12-15T08:33:16', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'ff43957f-cd77-456c-bc85-f36df82cf897'	System	15 Dec 2020 14:33:59
User entered 'No (N)'	System	15 Dec 2020 14:33:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

Have you been exposed to someone with 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 (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-12-15T08:33:26', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'ff43957f-cd77-456c-bc85-f36df82cf897'	System	15 Dec 2020 14:33:59
User entered 'No (N)'	System	15 Dec 2020 14:33:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-12-15T08:33:57', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'ff43957f-cd77-456c-bc85-f36df82cf897'	System	15 Dec 2020 14:33:59
User entered '15 Dec 2020 08:33:57'	System	15 Dec 2020 14:33:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[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 (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-12-21T18:53:37', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '39645b22-736b-41a3-8ab5-843b9d3386d6' User entered 'No (N)'	System	22 Dec 2020 00:54:01
	System	22 Dec 2020 00:54:01

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

Have you been exposed to someone with 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 (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-12-21T18:53:45', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '39645b22-736b-41a3-8ab5-843b9d3386d6'	System	22 Dec 2020 00:54:01
User entered 'No (N)'	System	22 Dec 2020 00:54:01

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-12-21T18:53:58', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '39645b22-736b-41a3-8ab5-843b9d3386d6' User entered '21 Dec 2020 18:53:58'	System	22 Dec 2020 00:54:01
	System	22 Dec 2020 00:54:01

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[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 (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-12-28T12:27:30', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '6def6296-4cfe-403d-baf7-3e214c7213b0'	System	28 Dec 2020 18:28:02
User entered 'No (N)'	System	28 Dec 2020 18:28:02

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

Have you been exposed to someone with 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 (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-12-28T12:27:37', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '6def6296-4cfe-403d-baf7-3e214c7213b0'	System	28 Dec 2020 18:28:02
User entered 'No (N)'	System	28 Dec 2020 18:28:02

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2020-12-28T12:27:58', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '6def6296-4cfe-403d-baf7-3e214c7213b0' User entered '28 Dec 2020 12:27:58'	System	28 Dec 2020 18:28:02
	System	28 Dec 2020 18:28:02

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[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 (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2021-01-07T14:59:33', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '292ef939-450f-4e80-be61-8f0f5af582c0' User entered 'No (N)'	System	07 Jan 2021 20:59:59
	System	07 Jan 2021 20:59:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

Have you been exposed to someone with 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 (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2021-01-07T14:59:44', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '292ef939-450f-4e80-be61-8f0f5af582c0' User entered 'No (N)'	System	07 Jan 2021 20:59:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2021-01-07T14:59:56', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '292ef939-450f-4e80-be61-8f0f5af582c0' User entered '07 Jan 2021 14:59:56'	System	07 Jan 2021 20:59:59
	System	07 Jan 2021 20:59:59

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[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 (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2021-01-10T13:24:32', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '05ce1e5e-dcf8-47bf-bdaf-325d14fab9f3'	System	10 Jan 2021 19:25:04
User entered 'No (N)'	System	10 Jan 2021 19:25:04

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

Have you been exposed to someone with 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 (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2021-01-10T13:24:41', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '05ce1e5e-dcf8-47bf-bdaf-325d14fab9f3'	System	10 Jan 2021 19:25:04
User entered 'No (N)'	System	10 Jan 2021 19:25:04

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2021-01-10T13:25:00', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '05ce1e5e-dcf8-47bf-bdaf-325d14fab9f3' User entered '10 Jan 2021 13:25:00'	System	10 Jan 2021 19:25:04
	System	10 Jan 2021 19:25:04

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[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 (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2021-01-19T08:16:58', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'fd311a73-871e-4e09-8f2c-88018a50a15b'	System	19 Jan 2021 14:17:17
User entered 'No (N)'	System	19 Jan 2021 14:17:17

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

Have you been exposed to someone with 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 (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2021-01-19T08:17:05', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'fd311a73-871e-4e09-8f2c-88018a50a15b'	System	19 Jan 2021 14:17:17
User entered 'No (N)'	System	19 Jan 2021 14:17:17

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2021-01-19T08:17:14', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'fd311a73-871e-4e09-8f2c-88018a50a15b' User entered '19 Jan 2021 08:17:14'	System	19 Jan 2021 14:17:17
	System	19 Jan 2021 14:17:17

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[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 (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2021-01-26T21:48:12', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '03c6014c-e9f7-4a61-b9fa-e710b0473325'	System	27 Jan 2021 03:48:38
User entered 'No (N)'	System	27 Jan 2021 03:48:38

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

Have you been exposed to someone with 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 (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2021-01-26T21:48:18', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '03c6014c-e9f7-4a61-b9fa-e710b0473325'	System	27 Jan 2021 03:48:38
User entered 'No (N)'	System	27 Jan 2021 03:48:38

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2021-01-26T21:48:28', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '03c6014c-e9f7-4a61-b9fa-e710b0473325' User entered '26 Jan 2021 21:48:28'	System	27 Jan 2021 03:48:38
	System	27 Jan 2021 03:48:38

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[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 (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2021-02-01T16:01:33', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '8c5343e4-b9ef-4a51-884e-14dc6fe5d6c9'	System	01 Feb 2021 22:01:56
User entered 'No (N)'	System	01 Feb 2021 22:01:56

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

Have you been exposed to someone with 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 (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2021-02-01T16:01:42', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '8c5343e4-b9ef-4a51-884e-14dc6fe5d6c9'	System	01 Feb 2021 22:01:56
User entered 'No (N)'	System	01 Feb 2021 22:01:56

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2021-02-01T16:01:53', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '8c5343e4-b9ef-4a51-884e-14dc6fe5d6c9' User entered '01 Feb 2021 16:01:53'	System	01 Feb 2021 22:01:56
	System	01 Feb 2021 22:01:56

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[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 (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2021-02-08T10:48:02', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'f53370d7-c30b-450e-a2b4-5abddc98488e'	System	08 Feb 2021 16:48:27
User entered 'No (N)'	System	08 Feb 2021 16:48:27

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

Have you been exposed to someone with 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 (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2021-02-08T10:48:08', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'f53370d7-c30b-450e-a2b4-5abddc98488e' User entered 'No (N)'	System	08 Feb 2021 16:48:27

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2021-02-08T10:48:22', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'f53370d7-c30b-450e-a2b4-5abddc98488e' User entered '08 Feb 2021 10:48:22'	System	08 Feb 2021 16:48:27
	System	08 Feb 2021 16:48:27

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[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 (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2021-02-15T00:33:57', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '3ee1f394-da4a-4db0-a625-cfd1023e3607'	System	15 Feb 2021 06:34:31
User entered 'No (N)'	System	15 Feb 2021 06:34:31

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

Have you been exposed to someone with 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 (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2021-02-15T00:34:09', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '3ee1f394-da4a-4db0-a625-cfd1023e3607' User entered 'No (N)'	System	15 Feb 2021 06:34:31

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2021-02-15T00:34:26', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '3ee1f394-da4a-4db0-a625-cfd1023e3607' User entered '15 Feb 2021 00:34:26'	System	15 Feb 2021 06:34:31
	System	15 Feb 2021 06:34:31

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[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 (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2021-02-22T15:15:27-06:00', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '1d7dd89e-8f1b-4f59-8d01-db34787469b2'	System	22 Feb 2021 21:15:48
User entered 'No (N)'	System	22 Feb 2021 21:15:48

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

Have you been exposed to someone with 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 (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2021-02-22T15:15:33-06:00', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '1d7dd89e-8f1b-4f59-8d01-db34787469b2'	System	22 Feb 2021 21:15:48
User entered 'No (N)'	System	22 Feb 2021 21:15:48

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2021-02-22T15:15:45-06:00', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '1d7dd89e-8f1b-4f59-8d01-db34787469b2'	System	22 Feb 2021 21:15:48
User entered '22 Feb 2021 21:15:45'	System	22 Feb 2021 21:15:48

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[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 (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2021-03-01T12:06:07-06:00', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '2d8520df-9914-47ac-9cae-7fbcfb13bf1d' User entered 'No (N)'	System	01 Mar 2021 18:14:51
	System	01 Mar 2021 18:14:51

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

Have you been exposed to someone with 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 (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2021-03-01T12:06:47-06:00', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '2d8520df-9914-47ac-9cae-7fbcfb13bf1d'	System	01 Mar 2021 18:14:51
User entered 'No (N)'	System	01 Mar 2021 18:14:51

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2021-03-01T12:07:03-06:00', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '2d8520df-9914-47ac-9cae-7fbcfb13bf1d'	System	01 Mar 2021 18:14:51
User entered '01 Mar 2021 12:07:03'	System	01 Mar 2021 18:14:51

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[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 (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2021-03-08T12:57:45-06:00', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '52ac77dc-d4cd-4339-b5b9-ea51564934de'	System	08 Mar 2021 18:58:07
User entered 'No (N)'	System	08 Mar 2021 18:58:07

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

Have you been exposed to someone with 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 (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2021-03-08T12:57:54-06:00', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '52ac77dc-d4cd-4339-b5b9-ea51564934de'	System	08 Mar 2021 18:58:07
User entered 'No (N)'	System	08 Mar 2021 18:58:07

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2021-03-08T12:58:04-06:00', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '52ac77dc-d4cd-4339-b5b9-ea51564934de' User entered '08 Mar 2021 12:58:04'	System	08 Mar 2021 18:58:07
	System	08 Mar 2021 18:58:07

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[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 (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2021-03-15T01:29:13-05:00', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '30451592-f308-438c-b509-90b6661a677f' User entered 'No (N)'	System	15 Mar 2021 06:29:45
	System	15 Mar 2021 06:29:45

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

Have you been exposed to someone with 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 (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2021-03-15T01:29:23-05:00', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '30451592-f308-438c-b509-90b6661a677f'	System	15 Mar 2021 06:29:45
User entered 'No (N)'	System	15 Mar 2021 06:29:45

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2021-03-15T01:29:40-05:00', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '30451592-f308-438c-b509-90b6661a677f' User entered '15 Mar 2021 01:29:40'	System	15 Mar 2021 06:29:45
	System	15 Mar 2021 06:29:45

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[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 (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2021-03-21T16:45:09-05:00', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '1c28b230-4399-480b-bf37-9ec674425ac8'	System	21 Mar 2021 21:45:28
User entered 'No (N)'	System	21 Mar 2021 21:45:28

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

Have you been exposed to someone with 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 (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2021-03-21T16:45:14-05:00', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '1c28b230-4399-480b-bf37-9ec674425ac8'	System	21 Mar 2021 21:45:28
User entered 'No (N)'	System	21 Mar 2021 21:45:28

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2021-03-21T16:45:26-05:00', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '1c28b230-4399-480b-bf37-9ec674425ac8' User entered '21 Mar 2021 16:45:26'	System	21 Mar 2021 21:45:28
	System	21 Mar 2021 21:45:28

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[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 (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2021-03-28T07:32:45-05:00', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'a723da5a-5424-4a85-ab3c-36742c0375d6'	System	28 Mar 2021 12:33:05
User entered 'No (N)'	System	28 Mar 2021 12:33:05

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

Have you been exposed to someone with 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 (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2021-03-28T07:32:53-05:00', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'a723da5a-5424-4a85-ab3c-36742c0375d6'	System	28 Mar 2021 12:33:05
User entered 'No (N)'	System	28 Mar 2021 12:33:05

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2021-03-28T07:33:00-05:00', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'a723da5a-5424-4a85-ab3c-36742c0375d6' User entered '28 Mar 2021 07:33:00'	System	28 Mar 2021 12:33:05
	System	28 Mar 2021 12:33:05

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[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 (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2021-04-07T16:06:45-05:00', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'c9e6fc21-e7a5-4dad-874b-5c6e2697b70a' User entered 'No (N)'	System	07 Apr 2021 21:07:18
	System	07 Apr 2021 21:07:18

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

Have you been exposed to someone with 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 (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2021-04-07T16:06:59-05:00', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'c9e6fc21-e7a5-4dad-874b-5c6e2697b70a' User entered 'No (N)'	System	07 Apr 2021 21:07:18
	System	07 Apr 2021 21:07:18

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2021-04-07T16:07:08-05:00', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'c9e6fc21-e7a5-4dad-874b-5c6e2697b70a' User entered '07 Apr 2021 16:07:08'	System	07 Apr 2021 21:07:18
	System	07 Apr 2021 21:07:18

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[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 (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2021-04-12T19:45:56-05:00', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'b75690c9-9392-4420-925f-8022ec2822dd'	System	13 Apr 2021 00:46:16
User entered 'No (N)'	System	13 Apr 2021 00:46:16

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

Have you been exposed to someone with 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 (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2021-04-12T19:46:03-05:00', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'b75690c9-9392-4420-925f-8022ec2822dd'	System	13 Apr 2021 00:46:16
User entered 'No (N)'	System	13 Apr 2021 00:46:16

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2021-04-12T19:46:12-05:00', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'b75690c9-9392-4420-925f-8022ec2822dd'	System	13 Apr 2021 00:46:16
User entered '12 Apr 2021 19:46:12'	System	13 Apr 2021 00:46:16

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[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 (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2021-04-18T10:07:21-05:00', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '95c9e46e-394e-4a37-904b-4a862672a6de' User entered 'No (N)'	System	18 Apr 2021 15:07:50
	System	18 Apr 2021 15:07:50

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

Have you been exposed to someone with 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 (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2021-04-18T10:07:39-05:00', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '95c9e46e-394e-4a37-904b-4a862672a6de'	System	18 Apr 2021 15:07:50
User entered 'No (N)'	System	18 Apr 2021 15:07:50

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2021-04-18T10:07:48-05:00', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '95c9e46e-394e-4a37-904b-4a862672a6de' User entered '18 Apr 2021 10:07:48'	System	18 Apr 2021 15:07:50
	System	18 Apr 2021 15:07:50

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[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 (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2021-04-27T17:36:40-05:00', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'e648bfae-3617-4104-b60f-00059c922c91'	System	28 Apr 2021 23:32:12
User entered 'No (N)'	System	28 Apr 2021 23:32:12

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

Have you been exposed to someone with 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 (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2021-04-27T17:36:52-05:00', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'e648bfae-3617-4104-b60f-00059c922c91'	System	28 Apr 2021 23:32:12
User entered 'No (N)'	System	28 Apr 2021 23:32:12

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2021-04-27T17:37:03-05:00', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: 'e648bfae-3617-4104-b60f-00059c922c91'	System	28 Apr 2021 23:32:12
User entered '27 Apr 2021 17:37:03'	System	28 Apr 2021 23:32:12

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[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 (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2021-05-03T06:34:37-05:00', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '293fed44-83e5-4128-ab6a-3fc96ffeee6f' User entered 'No (N)'	System	03 May 2021 11:35:01
	System	03 May 2021 11:35:01

US3312212

Folder: New Safety Follow Up Diary (1)

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Have you been exposed to someone with 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 (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2021-05-03T06:34:47-05:00', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '293fed44-83e5-4128-ab6a-3fc96ffeee6f' User entered 'No (N)'	System	03 May 2021 11:35:01
	System	03 May 2021 11:35:01

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2021-05-03T06:34:55-05:00', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '293fed44-83e5-4128-ab6a-3fc96ffeee6f'	System	03 May 2021 11:35:01
User entered '03 May 2021 06:34:55'	System	03 May 2021 11:35:01

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 00:41:03

US3312212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:02:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:41:03
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 00:41:03

US3312212

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:02:15

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:50:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2021-03-01T12:07:22-06:00', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '49c7d41c-1945-4f43-9e23-d30b97a84d79'	System	01 Mar 2021 18:15:09
User entered 'No (N)'	System	01 Mar 2021 18:15:09

US3312212

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:02:15

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:50:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7FCDB22E-1E4D-42E4-B4A1-FBC8A04B75A0)', Time: '2021-03-01T12:07:29-06:00', User OID: 'PatientReportedOutcome (US3312212)', ODM File OID: '49c7d41c-1945-4f43-9e23-d30b97a84d79' User entered '01 Mar 2021 12:07:29'	System	01 Mar 2021 18:15:09
	System	01 Mar 2021 18:15:09

US3312212

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:22:33

US3312212

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered '13 Nov 2020'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:22:33

US3312212

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:22:33

US3312212

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:15

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:22:33

US3312212

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:22:17

US3312212

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:08:40
User entered 'I'	System	17 Nov 2020 18:22:17

US3312212

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Dec 2020 19:12:32

US3312212

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered '17 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Dec 2020 19:12:32

US3312212

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	18 Dec 2020 19:12:32

US3312212

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:15

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 19:12:32

US3312212

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Dec 2020 19:12:37

US3312212

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:12:29
User entered 'I'	System	18 Dec 2020 19:12:37

US3312212

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:01:51

US3312212

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:15

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:01:51

US3312212

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:01:51

US3312212

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:15

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:01:51

US3312212

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:01:55

US3312212

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:12:29
User entered 'I'	System	22 Jan 2021 21:01:55

US3312212

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 15:17:52

US3312212

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:15

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered '12 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 15:17:52

US3312212

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 15:17:52

US3312212

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:15

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 15:17:52

US3312212

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 15:17:41

US3312212

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:12:29
User entered '1'	System	15 Feb 2021 15:17:41

US3312212

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:02:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:30:02

US3312212

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered '09 Mar 2021'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:30:02

US3312212

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:02:15

[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 07:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:30:02

US3312212

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:02:15

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:12:29
User entered 'VISIT4'	System	10 Mar 2021 18:30:02

US3312212

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:07:06

US3312212

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:07:06

US3312212

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:15

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:07:06

US3312212

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:15

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:12:29
User entered empty.	System	30 Mar 2021 14:07:06

US3312212

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:07:06

US3312212

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:07:06

US3312212

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:07:06

US3312212

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:07:06

US3312212

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:12:29
User entered empty.	System	30 Mar 2021 14:07:06

US3312212

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:07:06

US3312212

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:12:29
User entered empty.	System	30 Mar 2021 14:07:06

US3312212

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:07:06

US3312212

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:12:29
User entered empty.	System	30 Mar 2021 14:07:06

US3312212

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:07:06

US3312212

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:15

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:12:29
User entered empty.	System	30 Mar 2021 14:07:06

US3312212

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:15

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:12:29

US3312212

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:15

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:12:29

US3312212

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:02:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:30:32

US3312212

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:02:15

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:30:32

US3312212

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:29:37

US3312212

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:15

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered '09 Mar 2021'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:29:37

US3312212

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:15

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered '09:13'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:29:37

US3312212

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:15

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:12:29
User entered '09 Mar 2021 09:13'	System	10 Mar 2021 18:29:37

US3312212

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:12:29
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	10 Mar 2021 18:29:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Mar 2021 18:29:45
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Mar 2021 18:29:45
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Mar 2021 18:29:41
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 18:29:41

US3312212

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:12:29
User entered '1'	System	10 Mar 2021 18:29:45
User entered empty.	System	10 Mar 2021 18:29:41

US3312212

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 13:23:11

US3312212

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:00
User entered '13 Apr 2021'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 13:23:11

US3312212

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:00
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 13:23:11

US3312212

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:15

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:00
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 13:23:11

US3312212

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	15 Apr 2021 19:58:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 13:23:15

US3312212

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:15

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Apr 2021 13:23:15

US3312212

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

Form: Visit Date

Generated On: 09 Jun 2021 17:02:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:28:46

US3312212

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

Form: Visit Date

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:28:46

US3312212

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

Form: Visit Date

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:28:46

US3312212

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

Form: Visit Date

Generated On: 09 Jun 2021 17:02:15

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User entered 'UNBLND_DECIDE'	System	13 Jan 2021 16:28:46

US3312212

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

Form: Unblinding

Generated On: 09 Jun 2021 17:02:15

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:23:17

US3312212

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

Form: Unblinding

Generated On: 09 Jun 2021 17:02:15

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:29:37

US3312212

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

Form: Unblinding

Generated On: 09 Jun 2021 17:02:15

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:23:17

US3312212

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

Form: Unblinding

Generated On: 09 Jun 2021 17:02:15

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:29:37

US3312212

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

Form: Unblinding

Generated On: 09 Jun 2021 17:02:15

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:23:17

US3312212

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

Form: Unblinding

Generated On: 09 Jun 2021 17:02:15

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:23:17

US3312212

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

Form: Unblinding

Generated On: 09 Jun 2021 17:02:15

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 08:01:34
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	13 Jan 2021 16:23:17

US3312212

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

Form: Unblinding

Generated On: 09 Jun 2021 17:02:15

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4) System	20 Jan 2021 08:01:34
Comment added "Subject did not receive second dose of placebo. Placebo entered in order to populate additional decisions visit page".	(b) (4), (b) (6)	13 Jan 2021 16:23:59
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	13 Jan 2021 16:23:17

US3312212

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

Form: Unblinding

Generated On: 09 Jun 2021 17:02:15

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:23:17

US3312212

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

Form: Unblinding

Generated On: 09 Jun 2021 17:02:15

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User entered '1'	System	13 Jan 2021 16:23:17

US3312212

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

Form: Unblinding

Generated On: 09 Jun 2021 17:02:15

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User entered 'I'	System	13 Jan 2021 16:23:17

US3312212

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:02:15

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:26:24

US3312212

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:02:15

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:26:24

US3312212

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:02:15

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User entered empty.	System	13 Jan 2021 16:26:24
DataPoint set to visible.	System	13 Jan 2021 16:23:17

US3312212

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:02:15

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:26:24

US3312212

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:02:15

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:26:24

US3312212

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:02:15

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User entered empty.	System	13 Jan 2021 16:26:24
DataPoint set to visible.	System	13 Jan 2021 16:23:17

US3312212

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:15

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	13 Jan 2021 16:26:24

US3312212

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:26:24

US3312212

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:26:24

US3312212

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:15

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered '14:10'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:26:24

US3312212

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:15

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User entered '12 Jan 2021 14:10'	System	13 Jan 2021 16:26:24

US3312212

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered '98.2' F	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:26:24

US3312212

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:26:24

US3312212

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:26:24

US3312212

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered '54'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:26:24

US3312212

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User entered 'bpm'	System	13 Jan 2021 16:26:24

US3312212

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered '16'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:26:24

US3312212

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User entered 'breaths/min'	System	13 Jan 2021 16:26:24

US3312212

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered '125'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:26:24

US3312212

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User entered 'mmHg'	System	13 Jan 2021 16:26:24

US3312212

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:15

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered '67'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:26:24

US3312212

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:15

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User entered 'mmHg'	System	13 Jan 2021 16:26:24

US3312212

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:02:15

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:26:24

US3312212

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:02:15

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:26:24

US3312212

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:02:15

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User entered empty.	System	13 Jan 2021 16:26:24
DataPoint set to visible.	System	13 Jan 2021 16:23:17

US3312212

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:15

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	13 Jan 2021 16:26:24

US3312212

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:26:24

US3312212

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:26:24

US3312212

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:15

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered '15:48'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:26:24

US3312212

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:15

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User entered '12 Jan 2021 15:48'	System	13 Jan 2021 16:26:24

US3312212

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered '98.8' F	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:26:24

US3312212

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:26:24

US3312212

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:26:24

US3312212

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered '56'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:26:24

US3312212

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User entered 'bpm'	System	13 Jan 2021 16:26:24

US3312212

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered '14'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:26:24

US3312212

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User entered 'breaths/min'	System	13 Jan 2021 16:26:24

US3312212

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered '130'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:26:24

US3312212

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User entered 'mmHg'	System	13 Jan 2021 16:26:24

US3312212

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
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)	14 Jan 2021 08:51:32
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 'CONFIRMED CORRECT AS ENTERED. NCS NOT AN AE. DIASTOLIC LOW BP NOT ON TOXICITY TABLE.' (Site from System).	(b) (4), (b) (6)	13 Jan 2021 16:27:32
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).		13 Jan 2021 16:26:24
User entered '55'	(b) (4), (b) (6)	13 Jan 2021 16:26:24

US3312212

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:15

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User entered 'mmHg'	System	13 Jan 2021 16:26:24

US3312212

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:02:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:27:54

US3312212

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:02:15

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:27:54

US3312212

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

Form: Exposure

Generated On: 09 Jun 2021 17:02:15

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:28:31

US3312212

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

Form: Exposure

Generated On: 09 Jun 2021 17:02:15

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:28:31

US3312212

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

Form: Exposure

Generated On: 09 Jun 2021 17:02:15

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)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:28:31

US3312212

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

Form: Exposure

Generated On: 09 Jun 2021 17:02:15

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User entered 'mRNA-1273'	System	13 Jan 2021 16:28:31
DataPoint set to visible.	System	13 Jan 2021 16:23:17

US3312212

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

Form: Exposure

Generated On: 09 Jun 2021 17:02:15

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:28:31

US3312212

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

Form: Exposure

Generated On: 09 Jun 2021 17:02:15

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered '15:17'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:28:31

US3312212

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

Form: Exposure

Generated On: 09 Jun 2021 17:02:15

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User entered '12 Jan 2021 15:17'	System	13 Jan 2021 16:28:31

US3312212

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

Form: Exposure

Generated On: 09 Jun 2021 17:02:15

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:28:31

US3312212

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

Form: Exposure

Generated On: 09 Jun 2021 17:02:15

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User entered 'ONCE'	System	13 Jan 2021 16:28:31

US3312212

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

Form: Exposure

Generated On: 09 Jun 2021 17:02:15

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User entered 'INTRAMUSCULAR'	System	13 Jan 2021 16:28:31

US3312212

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:22:26

US3312212

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:15

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:22:26

US3312212

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:15

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered '13:47'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:22:26

US3312212

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:15

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User entered '12 Jan 2021 13:47'	System	13 Jan 2021 16:22:26

US3312212

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:02:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:22:37

US3312212

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:02:15

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:22:37

US3312212

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:02:15

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered '13:46'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:22:37

US3312212

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:02:15

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User entered '12 Jan 2021 13:46'	System	13 Jan 2021 16:22:37

US3312212

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

Form: Continuing

Generated On: 09 Jun 2021 17:02:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:28:52

US3312212

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

Form: Continuing

Generated On: 09 Jun 2021 17:02:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User entered 'I'	System	13 Jan 2021 16:28:52

US3312212

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:02:56

US3312212

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:15

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered '20 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:02:56

US3312212

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:02:56

US3312212

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:15

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:02:56

US3312212

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:03:02

US3312212

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User entered 'I'	System	22 Jan 2021 21:03:02

US3312212

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:15

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User entered '1'	System	22 Jan 2021 21:03:02
DataPoint set to visible.	System	22 Jan 2021 21:03:02

US3312212

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:02:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:46:34

US3312212

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered '09 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:46:34

US3312212

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:46:34

US3312212

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:02:15

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User entered 'OLD29'	System	11 Feb 2021 20:46:34

US3312212

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:15

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	11 Feb 2021 20:47:19

US3312212

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:47:19

US3312212

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered '09 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:47:19

US3312212

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:15

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered '13:29'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:47:19

US3312212

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:15

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User entered '09 Feb 2021 13:29'	System	11 Feb 2021 20:47:19

US3312212

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:15

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered '98.8' F	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:47:19

US3312212

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:47:19

US3312212

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:47:19

US3312212

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered '66'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:47:19

US3312212

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User entered 'bpm'	System	11 Feb 2021 20:47:19

US3312212

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered '14'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:47:19

US3312212

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User entered 'breaths/min'	System	11 Feb 2021 20:47:19

US3312212

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:15

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered '123'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:47:19

US3312212

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User entered 'mmHg'	System	11 Feb 2021 20:47:19

US3312212

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
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)	12 Feb 2021 15:03:15
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 'CONFIRMED CORRECT AS ENTERED. NCS NOT AN AE. DIASTOLIC LOW BP NOT ON TOXICITY TABLE.' (Site from System).	(b) (4), (b) (6)	11 Feb 2021 20:47:43
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).		11 Feb 2021 20:47:19
User entered '55'	(b) (4), (b) (6)	11 Feb 2021 20:47:19

US3312212

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:02:15

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User entered 'mmHg'	System	11 Feb 2021 20:47:19

US3312212

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:15

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	11 Feb 2021 20:47:19

US3312212

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:47:19

US3312212

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered '09 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:47:19

US3312212

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:15

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered '15:03'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:47:19

US3312212

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:15

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User entered '09 Feb 2021 15:03'	System	11 Feb 2021 20:47:19

US3312212

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:15

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered '98.1' F	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:47:19

US3312212

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:47:19

US3312212

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:47:19

US3312212

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered '61'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:47:19

US3312212

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User entered 'bpm'	System	11 Feb 2021 20:47:19

US3312212

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered '14'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:47:19

US3312212

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User entered 'breaths/min'	System	11 Feb 2021 20:47:19

US3312212

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered '119'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:47:19

US3312212

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User entered 'mmHg'	System	11 Feb 2021 20:47:19

US3312212

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
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)	12 Feb 2021 15:03:21
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 'CONFIRMED CORRECT AS ENTERED. NCS NOT AN AE. DIASTOLIC LOW BP NOT ON TOXICITY TABLE.' (Site from System).	(b) (4), (b) (6)	11 Feb 2021 20:47:50
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).		11 Feb 2021 20:47:19
User entered '58'	(b) (4), (b) (6)	11 Feb 2021 20:47:19

US3312212

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:02:15

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User entered 'mmHg'	System	11 Feb 2021 20:47:19

US3312212

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:02:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:47:59

US3312212

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:02:15

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered '09 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:47:59

US3312212

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:15

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:48:12

US3312212

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:15

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:48:12

US3312212

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:15

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)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:48:12

US3312212

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:15

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User entered 'mRNA-1273'	System	11 Feb 2021 20:48:12
DataPoint set to visible.	System	22 Jan 2021 21:03:02

US3312212

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:15

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered '09 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:48:12

US3312212

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:15

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered '14:32'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:48:12

US3312212

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:15

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User entered '09 Feb 2021 14:32'	System	11 Feb 2021 20:48:12

US3312212

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:15

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User closed query "Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose." (Site from System).	(b) (4) (b) (4), (b) (6)	09 Mar 2021 10:32:30
Query "Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose." answered with 'DOSED IN DOMINANT ARM DUE TO GLUCOMETER ON LEFT ARM.' (Site from System).	(b) (4), (b) (6)	05 Mar 2021 16:19:01
Amendment Manager: User opened query "Treatment System Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose." (Site from System).		17 Feb 2021 01:19:26
User entered 'Right Arm (RIGHT ARM)'	(b) (4), (b) (6)	11 Feb 2021 20:48:12

US3312212

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:15

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User entered 'ONCE'	System	11 Feb 2021 20:48:12

US3312212

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:02:15

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User entered 'INTRAMUSCULAR'	System	11 Feb 2021 20:48:12

US3312212

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:48:15

US3312212

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User entered 'I'	System	11 Feb 2021 20:48:15

US3312212

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:28:35

US3312212

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered '16 Feb 2021'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:28:35

US3312212

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:28:35

US3312212

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:02:15

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:28:35

US3312212

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:28:39

US3312212

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:02:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User entered 'I'	System	17 Feb 2021 15:28:39

US3312212

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:02:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:28:49

US3312212

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered '09 Mar 2021'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:28:49

US3312212

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:28:49

US3312212

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:02:15

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User entered 'OLD57'	System	10 Mar 2021 18:28:49

US3312212

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:28:56

US3312212

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:28:56

US3312212

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:15

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:28:56

US3312212

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:15

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User entered empty.	System	10 Mar 2021 18:28:56

US3312212

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:28:56

US3312212

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:28:56

US3312212

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:28:56

US3312212

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:28:56

US3312212

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User entered empty.	System	10 Mar 2021 18:28:56

US3312212

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:28:56

US3312212

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User entered empty.	System	10 Mar 2021 18:28:56

US3312212

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:15

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:28:56

US3312212

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User entered empty.	System	10 Mar 2021 18:28:56

US3312212

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:15

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:28:56

US3312212

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:15

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User entered empty.	System	10 Mar 2021 18:28:56

US3312212

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:15

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33

US3312212

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:02:15

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33

US3312212

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:02:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:28:59

US3312212

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:02:15

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:28:59

US3312212

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:29:08

US3312212

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:15

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered '09 Mar 2021'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:29:08

US3312212

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:15

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered '09:13'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:29:08

US3312212

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:02:15

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:15:33
User entered '09 Mar 2021 09:13'	System	10 Mar 2021 18:29:08

US3312212

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:02:15

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:25:51
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:51:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:50:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Sep 2020 00:44:04

US3312212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:15

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:51:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:34:14
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:52:20
User entered	System	07 Sep 2020 20:51:44
'USA-US300-2020-mRNA-1273-P301000002'		
User entered 'New'	(b) (4), (b) (6)	07 Sep 2020 20:51:44

US3312212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:15

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:51:27
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Bone and joint infections, PT: Osteomyelitis, LLT: Osteomyelitis of the foot - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	12 Mar 2021 15:11:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. DataPoint Verified.	Coder Import (b) (4)	12 Mar 2021 15:11:46
User closed query 'Per MM, please confirm "action taken with IP". If the event is present around the time scheduled for dosing, the participant may be injected at a later date, as per protocol 7.2 ' (Site from DM). Query 'Per MM, please confirm "action taken with IP". If the event is present around the time scheduled for dosing, the participant may be injected at a later date, as per protocol 7.2 ' answered with 'subject not medical stable with PICC line and IV antibiotics at the time of dose 2' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 19:32:52
User opened query 'Per MM, please confirm "action taken with IP". If the event is present around the time scheduled for dosing, the participant may be injected at a later date, as per protocol 7.2 ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 18:35:17
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Bone and joint infections, PT: Osteomyelitis, LLT: Osteomyelitis - version MedDRA\23.0.	(b) (4), (b) (6)	09 Nov 2020 22:18:59
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. Data point term sent to Coder	(b) (4), (b) (6)	29 Oct 2020 19:37:17
User entered 'Left Great toe osteomyelitis'	(b) (4), (b) (6)	05 Sep 2020 06:47:47
	Coder Import (b) (4)	05 Sep 2020 06:47:47
	(b) (4)	05 Sep 2020 06:47:47
	System	05 Sep 2020 00:50:08
	(b) (4), (b) (6)	05 Sep 2020 00:49:32

US3312212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:15

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:51:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:32:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Sep 2020 00:49:32

US3312212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:15

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:51:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:34:11
User entered 'No (N)'	(b) (4), (b) (6)	05 Sep 2020 00:49:32

US3312212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:15

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:51:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:34:17
User entered 'No (N)'	(b) (4), (b) (6)	05 Sep 2020 00:49:32

US3312212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:51:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:34:18
User entered '04 Sep 2020'	(b) (4), (b) (6)	05 Sep 2020 00:49:32

US3312212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:15

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:51:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:34:22
User entered empty.	(b) (4), (b) (6)	05 Sep 2020 00:49:32

US3312212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:15

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Sep 2020 00:49:32

US3312212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:51:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:34:21
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	09 Nov 2020 22:35:17
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 22:35:17
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	09 Nov 2020 22:34:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Sep 2020 00:49:32

US3312212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:15

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:51:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:44:51
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	09 Nov 2020 22:34:53
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	09 Nov 2020 22:34:53
User entered '16 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 22:34:53
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	09 Nov 2020 22:19:57
User entered empty.	(b) (4), (b) (6)	05 Sep 2020 00:49:32

US3312212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:15

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:51:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:44:52
User entered empty.	(b) (4), (b) (6)	05 Sep 2020 00:49:32

US3312212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:15

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV query: Please provide the stop date, when available. Please do not response to this query until the event has ended.' canceled (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 15:32:04
User opened query 'PV query: Please provide the stop date, when available. Please do not response to this query until the event has ended.' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 18:02:59
User entered empty.	System	05 Sep 2020 00:49:32

US3312212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:15

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:51:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:44:53
User closed query 'PV Query: As event required hospitalization, please consider upgrading intensity to grade 3. If not updated, please clarify.' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 17:09:02
Query 'PV Query: As event required hospitalization, please consider upgrading intensity to grade 3. If not updated, please clarify.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 15:13:19
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: New Information	(b) (4), (b) (6)	17 Sep 2020 15:13:09
User opened query 'PV Query: As event required hospitalization, please consider upgrading intensity to grade 3. If not updated, please clarify.' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 18:02:29
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	05 Sep 2020 00:49:32

US3312212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:15

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:51:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:44:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Sep 2020 00:49:32

US3312212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:15

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:51:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:45:04
User entered '0'	(b) (4), (b) (6)	05 Sep 2020 00:49:32

US3312212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:15

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:51:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:45:02
User entered '0'	(b) (4), (b) (6)	05 Sep 2020 00:49:32

US3312212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:51:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:44:59
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	14 Sep 2020 06:49:53
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 'Still hospitalized at this time' (Site from System).	(b) (4), (b) (6)	05 Sep 2020 00:50:30
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	05 Sep 2020 00:49:32
User entered 'I'	(b) (4), (b) (6)	05 Sep 2020 00:49:32

US3312212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:15

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:51:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 22:22:24
User closed query 'Per hospital records subject was admitted to hospital 03Sep2020. Please verify admission date and update source and EDC as needed.' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 22:22:22
Query 'Per hospital records subject was admitted to hospital 03Sep2020. Please verify admission date and update source and EDC as needed.' answered with 'updated ' (Site from CRA).	Monica Atwood (b) (4)	24 Nov 2020 22:13:46
User entered '03 Sep 2020' reason for change: Data Entry Error	(b) (4)	24 Nov 2020 22:12:27
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 20:51:25
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:50:59
User opened query 'Per hospital records subject was admitted to hospital 03Sep2020. Please verify admission date and update source and EDC as needed.' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 19:32:22
User entered '04 Sep 2020'	(b) (4), (b) (6)	05 Sep 2020 00:49:32

US3312212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:15

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:51:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:45:07
User closed query 'PV query: Please provide the discharge date, when available.' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 17:09:09
Query 'PV query: Please provide the discharge date, when available.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 15:12:51
User entered '09 Sep 2020' reason for change: New Information	(b) (4), (b) (6)	17 Sep 2020 15:10:25
User opened query 'PV query: Please provide the discharge date, when available.' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 18:03:28
User entered empty.	(b) (4), (b) (6)	05 Sep 2020 00:49:32

US3312212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:15

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:51:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:45:08
User entered 'No (N)'	(b) (4), (b) (6)	05 Sep 2020 00:49:32

US3312212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:15

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:51:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:45:10
User entered empty.	(b) (4), (b) (6)	05 Sep 2020 00:49:32

US3312212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:51:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:45:12
User entered '0'	(b) (4), (b) (6)	05 Sep 2020 00:49:32

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Folder: Adverse Events

Form: Adverse Events (1)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:51:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:45:13
User entered '0'	(b) (4), (b) (6)	05 Sep 2020 00:49:32

US3312212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:15

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:51:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:45:15
User entered '0'	(b) (4), (b) (6)	05 Sep 2020 00:49:32

US3312212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:15

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:51:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:45:16
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	05 Sep 2020 00:49:32

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:51:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:45:18
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	05 Sep 2020 00:49:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:15

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:51:27
DataPoint Verified.	(b) (4)	24 Nov 2020 19:45:20
	(b) (4), (b) (6)	
User closed query 'PV Query: Please clarify action taken as currently reported as none; however, narrative reports that dose 2 was withheld. Please update action taken as applicable.' (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 14:53:55
User closed query 'Action taken with investigational product is recorded as 'none' but in dosing discontinuation form this ae 'LEFT GREAT TOE OSTEOMYELITIS' is recorded as reason for study discontinuation. Kindly consider to update Action taken with investigational product as 'drug withdrawn' else clarify.' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 08:53:38
Query 'PV Query: Please clarify action taken as currently reported as none; however, narrative reports that dose 2 was withheld. Please update action taken as applicable.' answered with 'UPDATED' (Site from Safety).	Karol Moore (b) (4)	07 Oct 2020 00:30:16
	(b) (4)	
Query 'Action taken with investigational product is recorded as 'none' but in dosing discontinuation form this ae 'LEFT GREAT TOE OSTEOMYELITIS' is recorded as reason for study discontinuation. Kindly consider to update Action taken with investigational product as 'drug withdrawn' else clarify.' answered with 'UPDATED' (Site from DM).	Karol Moore (b) (4)	07 Oct 2020 00:30:09
	(b) (4)	
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Karol Moore (b) (4)	07 Oct 2020 00:29:33
	(b) (4)	
User opened query 'PV Query: Please clarify action taken as currently reported as none; however, narrative reports that dose 2 was withheld. Please update action taken as applicable.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 12:42:41
User opened query 'Action taken with investigational product is recorded as 'none' but in dosing discontinuation form this ae 'LEFT GREAT TOE OSTEOMYELITIS' is recorded as reason for study discontinuation. Kindly consider to update Action taken with investigational product as 'drug withdrawn' else clarify.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 09:22:27

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Folder: Adverse Events

Form: Adverse Events (1)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	(b) (4), (b) (6)	05 Sep 2020 00:49:32

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Folder: Adverse Events

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[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:51:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:45:26
User entered '0'	(b) (4), (b) (6)	05 Sep 2020 00:49:32

US3312212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:15

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:51:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:45:23
User entered '1' reason for change: Data Entry Error	Karol Moore (b) (4)	07 Oct 2020 00:29:51
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Sep 2020 00:49:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:15

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:51:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:45:24
User closed query 'Per DM CLR: Other Action Taken = Con Proc. However there is no Concomitant Procedure or Non-Drug Therapy recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate (i.e., CT Scan and Toe amputation per SAE narrative) or update action taken.' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 17:03:41
Query 'Per DM CLR: Other Action Taken = Con Proc. However there is no Concomitant Procedure or Non-Drug Therapy recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate (i.e., CT Scan and Toe amputation per SAE narrative) or update action taken.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 13:34:21
User opened query 'Per DM CLR: Other Action Taken = Con Proc. However there is no Concomitant Procedure or Non-Drug Therapy recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate (i.e., CT Scan and Toe amputation per SAE narrative) or update action taken.' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 00:10:06
User entered 'I'	(b) (4), (b) (6)	05 Sep 2020 00:49:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:15

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:51:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:45:27
User closed query 'PV query: Please provide the final outcome, when available. If the event has resolved with sequelae please state the sequelae (i.e. toe amputation). Please do not close this query until the event has ended.' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 16:36:15
Query 'PV query: Please provide the final outcome, when available. If the event has resolved with sequelae please state the sequelae (i.e. toe amputation). Please do not close this query until the event has ended.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 22:35:09
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 22:19:57
User opened query 'PV query: Please provide the final outcome, when available. If the event has resolved with sequelae please state the sequelae (i.e. toe amputation). Please do not close this query until the event has ended.' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 15:57:20
Query 'PV query: Please provide the final outcome, when available. If the event has resolved with sequelae please state the sequelae (i.e. toe amputation). Please do not close this query until the event has ended.' canceled (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 14:53:50
User opened query 'PV query: Please provide the final outcome, when available. If the event has resolved with sequelae please state the sequelae (i.e. toe amputation). Please do not close this query until the event has ended.' (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 16:06:34
User closed query 'PV query: Please provide the final outcome, when available. If the event has resolved with sequelae please state the sequelae (i.e. toe amputation). Please do not close this query until the event has ended. ' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 17:09:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:15

[Outcome](#)

Audit	User	Time (GMT)
Query 'PV query: Please provide the final outcome, when available. If the event has resolved with sequelae please state the sequelae (i.e. toe amputation). Please do not close this query until the event has ended. ' answered with 'ongoing' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 15:17:45
User opened query 'PV query: Please provide the final outcome, when available. If the event has resolved with sequelae please state the sequelae (i.e. toe amputation). Please do not close this query until the event has ended. ' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 18:04:04
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	05 Sep 2020 00:49:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:15

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:51:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:45:29
User entered 'recovered with sequelae left great toe amputation' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 22:19:57
User entered empty.	(b) (4), (b) (6)	05 Sep 2020 00:49:32

US3312212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:15

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:51:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:45:45
User closed query 'Per DM CLR: SAE Narrative indicates that there was a Zoster Rash on the Gluteal Cleft. However, there is no corresponding AE record that match this information. Please update to record the corresponding AE as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 20:55:18
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 16:36:24
User closed query 'PV Query: Please clarify if intravenous ceftaroline was started on 03 Sep 2020, prior to hospital admission. If so, please clarify. If not, please update CM eCRF with correct start date' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 16:36:22
User closed query 'PV Query: Please provide additional information on the IV antibiotics administered, including dosage and start date.' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 16:36:21
Query 'Per DM CLR: SAE Narrative indicates that there was a Zoster Rash on the Gluteal Cleft. However, there is no corresponding AE record that match this information. Please update to record the corresponding AE as appropriate. Otherwise, clarify. ' answered with 'ae has been updated to include herpes zoster' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 22:17:57
Query 'PV Query: Please provide additional information on the IV antibiotics administered, including dosage and start date.' answered with 'updated cm log' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 22:17:36
Query 'PV Query: Please clarify if intravenous ceftaroline was started on 03 Sep 2020, prior to hospital admission. If so, please clarify. If not, please update CM eCRF with correct start date' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 22:14:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:15

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'negative covid 19 test pre-op' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 22:09:19
User opened query 'Per DM CLR: SAE Narrative indicates that there was a Zoster Rash on the Gluteal Cleft. However, there is no corresponding AE record that match this information. Please update to record the corresponding AE as appropriate. Otherwise, clarify.	(b) (4), (b) (6)	20 Oct 2020 05:31:56
' (Site from DM).		
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 15:57:43
User opened query 'PV Query: Please clarify if intravenous ceftaroline was started on 03 Sep 2020, prior to hospital admission. If so, please clarify. If not, please update CM eCRF with correct start date' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 15:57:36
User opened query 'PV Query: Please provide additional information on the IV antibiotics administered, including dosage and start date.' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 15:57:28
Query 'PV Query: Please provide additional information on the IV antibiotics administered, including dosage and start date.' canceled (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 14:53:47
Query 'PV Query: Please clarify if intravenous ceftaroline was started on 03 Sep 2020, prior to hospital admission. If so, please clarify. If not, please update CM eCRF with correct start date.' canceled (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 14:53:44
User closed query 'PV Query: Please consider reporting herpes zoster as separate AE/SAE.' (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 14:53:39
Query 'PV Query: Please consider reporting herpes zoster as separate AE/SAE.' answered with 'UPDATED. ADDED AS AN AE' (Site from Safety).	Karol Moore (b) (4) (b) (4)	07 Oct 2020 00:31:40

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: SAE Narrative = Chronic Wound Left Great Toe. Please review and determine if this is considered a separate event and is clinically significant to be recorded in the subjects Medical History. If yes, please review and ensure that this is recorded in the MH eCRF. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 17:03:57
User opened query 'PV Query: Please consider reporting herpes zoster as separate AE/SAE.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 12:43:20
User opened query 'PV Query: Please clarify if intravenous ceftaroline was started on 03 Sep 2020, prior to hospital admission. If so, please clarify. If not, please update CM eCRF with correct start date.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 12:43:07
Query 'PV Query: Please provide any relevant laboratory (WBC, CRP, cultures, etc.) and diagnostic test results. Please include units and reference ranges if applicable. Please leave query open until information available.' canceled (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 12:41:30
Query 'PV Query: Please confirm if "chronic wound to left great toe" is considered med history (prior to start of study). If so, please add to MH eCRF page.' canceled (Site from Safety).	(b) (4), (b) (6)	30 Sep 2020 15:23:23
User opened query 'PV Query: Please provide additional information on the IV antibiotics administered, including dosage and start date.' (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 16:08:59
User opened query 'PV Query: Please confirm if "chronic wound to left great toe" is considered med history (prior to start of study). If so, please add to MH eCRF page.' (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 16:08:32
User opened query 'PV Query: Please provide any relevant laboratory (WBC, CRP, cultures, etc.) and diagnostic test results. Please include units and reference ranges if applicable. Please leave query open until information available.' (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 16:07:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:15

[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: SAE Narrative = Chronic Wound Left Great Toe. Please review and determine if this is considered a separate event and is clinically significant to be recorded in the subjects Medical History. If yes, please review and ensure that this is recorded in the MH eCRF. Otherwise, provide clarification. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 13:33:52

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User entered '71YR OLD DIABETIC WITH HISTORY OF LYMPHEDEMA BILATERAL LOWER EXTREMITIES, AND CHRONIC WOUND LEFT GREAT TOE THOUGHT TO BE NEARLY RESOLVED BUT UNFORTUNATELY FOUND TO HAVE DEEP FISTULA ON FOLLOW UP 03SEP2020. CT SCAN 04SEP2020 REVEALED OSTEOMYELITIS (NOT RELATE TO STUDY PRODUCT/PROCEDURE). TOE AMPUTATION PERFORMED ON SAME DAY WITH PLANS FOR HOSPITAL DISCHARGE ON 06SEP2020. SUBJECT REPORTED FEELING WELL, VOICE AND MOOD ROBUST ON PHONE, WILL REQUEST MEDICAL RECORDS AND FOLLOW. UPDATE: SUBJECT DISCHARGED FROM HOSPITAL 09SEP2020-AS HOLIDAY WEEKEND DELAYED COLLABORATION WITH HOME HEALTH AGENCY. HAS PICC LINE AND RECEIVING IV ANBTIBIOTICS FOR PLANNED APPROX 5 WEEKS. SEEING WOUND CARE SPECIALIST WEEKLY. MEDICAL RECORDS PENDING. Update 24Sep2020: Medical records received-confirmed above. Also medical history not previously reported by subject: stage IV CKD, chronic diastolic heart failure, valvular heart disease, NSTEMI, previous osteomyelitis in same area a few months ago. Cultures on hospital admission grew MRSA, ceftaroline IV via PICC line and discharged with PICC for antibiotics x 6 wks. Glucose ranged from 86-209 during hospitalization. Vesicular rash noted at gluteal cleft diagnosed as zoster rash and treated with oral acyclovir. At day 29 study visit-subject was cheerful, alert, wearing left surgical boot, rash scabbed and dry VS stable. Dose 2 withheld.' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 13:33:37

US3312212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:15

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: SAE Narrative = Chronic Wound Left Great Toe. Please review and determine if this is considered a separate event and is clinically significant to be recorded in the subjects Medical History. If yes, please review and ensure that this is recorded in the MH eCRF. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 00:10:17
User closed query 'PV Query: Please confirm if "chronic wound to left great toe" is considered med history (prior to start of study). If so, please add to MH eCRF page.' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 17:09:26
User closed query 'PV Query: Please provide any relevant laboratory (WBC, CRP, cultures, etc.) and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 17:09:23
User closed query 'PV Query: Please provide additional treatment for the event (pain medication, antibiotics, wound care, etc.). Please add medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 17:09:20
Query 'PV Query: Please provide additional treatment for the event (pain medication, antibiotics, wound care, etc.). Please add medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' answered with 'medical records pending' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 15:17:39

US3312212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:15

[Narrative](#)

Audit	User	Time (GMT)
User entered '71YR OLD DIABETIC WITH HISTORY OF LYMPHEDEMA BILATERAL LOWER EXTREMITIES, AND CHRONIC WOUND LEFT GREAT TOE THOUGHT TO BE NEARLY RESOLVED BUT UNFORTUNATELY FOUND TO HAVE DEEP FISTULA ON FOLLOW UP 03SEP2020. CT SCAN 04SEP2020 REVEALED OSTEOMYELITIS (NOT RELATE TO STUDY PRODUCT/PROCEDURE). TOE AMPUTATION PERFORMED ON SAME DAY WITH PLANS FOR HOSPITAL DISCHARGE ON 06SEP2020. SUBJECT REPORTED FEELING WELL, VOICE AND MOOD ROBUST ON PHONE, WILL REQUEST MEDICAL RECORDS AND FOLLOW. Update: Subject discharged from hospital 09Sep2020-as holiday weekend delayed collaboration with home health agency. Has PICC line and receiving IV antibiotics for planned approx 5 weeks. Seeing wound care Specialist weekly. Medical Records pending' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 15:17:28
Query 'PV Query: Please confirm if "chronic wound to left great toe" is considered med history (prior to start of study). If so, please add to MH eCRF page.' answered with 'medical history updated' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 15:12:41
Query 'PV Query: Please provide any relevant laboratory (WBC, CRP, cultures, etc.) and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Medical records pending' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 15:12:27
User opened query 'PV Query: Please confirm if "chronic wound to left great toe" is considered med history (prior to start of study). If so, please add to MH eCRF page.' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 18:05:52
User opened query 'PV Query: Please provide any relevant laboratory (WBC, CRP, cultures, etc.) and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 18:05:13

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide additional treatment for the event (pain medication, antibiotics, wound care, etc.). Please add medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 18:04:40
User entered '71yr old diabetic with history of lymphedema bilateral lower extremities, and chronic wound left great toe thought to be nearly resolved but unfortunately found to have deep fistula on follow up 03Sep2020. CT scan 04Sep2020 revealed osteomyelitis (not relate to Study product/procedure). Toe amputation performed on same day with plans for hospital discharge on 06Sep2020. Subject reported feeling well, voice and mood robust on phone, Will request medical records and follow.'	(b) (4), (b) (6)	05 Sep 2020 00:49:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:15

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Sep 2020 00:49:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:15

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Sep 2020 00:49:32

US3312212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:02:15

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Sep 2020 00:49:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:02:15

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:32:21

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:02:15

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:32:21
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:51:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:50:59
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Herpes zoster, LLT: Herpes zoster - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Oct 2020 00:32:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Oct 2020 00:32:20
Data point term sent to Coder	System	07 Oct 2020 00:31:39
User entered 'HERPES ZOSTER'	Karol Moore (b) (4) (b) (4)	07 Oct 2020 00:31:13

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:02:15

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:32:21
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:51:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:50:59
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	07 Oct 2020 00:31:13

US3312212

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:02:15

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:32:21
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:51:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:50:59
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	07 Oct 2020 00:31:13

US3312212

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:02:15

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:32:21
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:51:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:50:59
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	07 Oct 2020 00:31:13

US3312212

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:32:21
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:51:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:50:59
User entered '28 Aug 2020'	Karol Moore (b) (4) (b) (4)	07 Oct 2020 00:31:13

US3312212

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:02:15

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:32:21
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:51:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:50:59
User entered empty.	Karol Moore (b) (4) (b) (4)	07 Oct 2020 00:31:13

US3312212

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:02:15

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:32:21
User entered empty.	System	07 Oct 2020 00:31:13

US3312212

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:02:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:32:21
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:51:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:22:50
User closed query 'Per source AE has stop date. Please verify and update if needed.' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 22:22:49
Query 'Per source AE has stop date. Please verify and update if needed.' answered with 'updated' (Site from CRA).	Monica Atwood (b) (4) (b) (4)	24 Nov 2020 22:15:55
User entered 'No (N)' reason for change: Data Entry Error	Monica Atwood (b) (4) (b) (4)	24 Nov 2020 22:15:45
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 20:51:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:50:59
User opened query 'Per source AE has stop date. Please verify and update if needed.' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 19:47:34
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	07 Oct 2020 00:31:13

US3312212

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:02:15

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:32:21
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:51:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:22:51
User entered '06 Nov 2020' reason for change: Data Entry Error	Monica Atwood (b) (4)	24 Nov 2020 22:15:45
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:51:04
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:50:59
User entered empty.	Karol Moore (b) (4) (b) (4)	07 Oct 2020 00:31:13

US3312212

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:02:15

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:32:21
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:51:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:50:59
User entered empty.	Karol Moore (b) (4) (b) (4)	07 Oct 2020 00:31:13

US3312212

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:02:15

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:32:21
User entered empty.	System	07 Oct 2020 00:31:13

US3312212

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:02:15

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:32:21
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:51:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:50:59
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Karol Moore (b) (4) (b) (4)	07 Oct 2020 00:31:13

US3312212

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:02:15

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:32:21
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:51:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:50:59
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	07 Oct 2020 00:31:13

US3312212

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:02:15

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:32:21
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:51:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:50:59
User entered '0'	Karol Moore (b) (4) (b) (4)	07 Oct 2020 00:31:13

US3312212

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:02:15

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:32:21
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:51:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:50:59
User entered '0'	Karol Moore (b) (4) (b) (4)	07 Oct 2020 00:31:13

US3312212

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:02:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:32:21
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:51:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:50:59
User entered '0'	Karol Moore (b) (4) (b) (4)	07 Oct 2020 00:31:13

US3312212

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:02:15

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:32:21
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:51:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:50:59
User entered empty.	Karol Moore (b) (4) (b) (4)	07 Oct 2020 00:31:13

US3312212

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:02:15

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:32:21
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:51:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:50:59
User entered empty.	Karol Moore (b) (4) (b) (4)	07 Oct 2020 00:31:13

US3312212

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:02:15

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:32:21
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:51:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:50:59
User entered empty.	Karol Moore (b) (4) (b) (4)	07 Oct 2020 00:31:13

US3312212

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:02:15

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:32:21
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:51:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:50:59
User entered empty.	Karol Moore (b) (4) (b) (4)	07 Oct 2020 00:31:13

US3312212

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:02:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:32:21
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:51:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:50:59
User entered '0'	Karol Moore (b) (4) (b) (4)	07 Oct 2020 00:31:13

US3312212

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:02:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:32:21
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:51:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:50:59
User entered '0'	Karol Moore (b) (4) (b) (4)	07 Oct 2020 00:31:13

US3312212

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:02:15

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:32:21
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:51:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:50:59
User entered '0'	Karol Moore (b) (4) (b) (4)	07 Oct 2020 00:31:13

US3312212

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:02:15

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:32:21
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:51:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:50:59
User entered 'Not Related (NOT RELATED)'	Karol Moore (b) (4) (b) (4)	07 Oct 2020 00:31:13

US3312212

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:02:15

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:32:21
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:51:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:50:59
User entered 'Not Related (NOT RELATED)'	Karol Moore (b) (4) (b) (4)	07 Oct 2020 00:31:13

US3312212

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:02:15

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:32:21
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:51:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:50:59
User entered 'Not Applicable (NOT APPLICABLE)'	Karol Moore (b) (4) (b) (4)	07 Oct 2020 00:31:13

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:02:15

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:32:21
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:51:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:50:59
User entered '0'	Karol Moore (b) (4) (b) (4)	07 Oct 2020 00:31:13

US3312212

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:02:15

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:32:21
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:51:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:50:59
User entered 'l'	Karol Moore (b) (4) (b) (4)	07 Oct 2020 00:31:13

US3312212

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:02:15

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:32:21
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:51:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:50:59
User entered '0'	Karol Moore (b) (4) (b) (4)	07 Oct 2020 00:31:13

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:02:15

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:32:21
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:44:06
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:51:27
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	
Data Entry Error	Monica Atwood (b) (4)	24 Nov 2020 22:15:45
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 20:51:13
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:50:59
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Karol Moore (b) (4)	07 Oct 2020 00:31:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:02:15

[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 11:32:21
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:51:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:50:59
User entered empty.	Karol Moore (b) (4) (b) (4)	07 Oct 2020 00:31:13

US3312212

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:02:15

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:32:21
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:51:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:50:59
User entered empty.	Karol Moore (b) (4) (b) (4)	07 Oct 2020 00:31:13

US3312212

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:02:15

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:32:21
User entered '0'	System	07 Oct 2020 00:31:13

US3312212

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:02:15

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:32:21
User entered 'I'	System	07 Oct 2020 00:31:13

US3312212

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:02:15

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:32:21

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:25:51
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:56:03
User closed query 'Per ETRTR: Please confirm whether ConMed was dosed at hospital or after discharge for SAE "Left great toe osteomyelitis", if yes ensure reporting in ConMeds, thanks.' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 19:47:48
Query 'Per ETRTR: Please confirm whether ConMed was dosed at hospital or after discharge for SAE "Left great toe osteomyelitis", if yes ensure reporting in ConMeds, thanks.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	25 Sep 2020 00:51:26
User opened query 'Per ETRTR: Please confirm whether ConMed was dosed at hospital or after discharge for SAE "Left great toe osteomyelitis", if yes ensure reporting in ConMeds, thanks.' (Site from CRA).	(b) (4), (b) (6)	15 Sep 2020 19:18:00
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:11:12

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:02:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 20:49:47
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN GLARGINE, PRODUCTSYNONYM: LANTUS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Aug 2020 17:14:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Aug 2020 17:14:40
Data point term sent to Coder	System	28 Aug 2020 17:13:18
User entered 'lantus'	Karol Moore (b) (4)	28 Aug 2020 17:12:33
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:02:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:12:33

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:02:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'Type II Diabetes Mellitus'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:12:33

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:02:15

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered '50'	Karol Moore (b) (4)	28 Aug 2020 17:12:33
	(b) (4)	

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:02:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:12:33

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:02:15

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered empty.	Karol Moore (b) (4)	28 Aug 2020 17:12:33
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:02:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'other (OTHER)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:12:33

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:02:15

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'nightyl before bed'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:12:33

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:02:15

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'Subcutaneous (SUBCUTANEOUS)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:12:33

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:02:15

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:12:33

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:02:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'un UNK 1990'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:12:33

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:02:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered '0'	Karol Moore (b) (4)	28 Aug 2020 17:12:33
	(b) (4)	

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:02:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:12:33

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:02:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:12:33

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:02:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:12:33

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:02:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Aug 2020 17:12:33

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:02:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Aug 2020 17:12:33

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:02:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Aug 2020 17:12:33

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:02:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 20:49:47
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN ASPART, PRODUCTSYNONYM: NOVOLOG - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Aug 2020 07:24:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Aug 2020 07:24:32
Data point term sent to Coder	System	28 Aug 2020 17:13:18
User entered 'novalog'	Karol Moore (b) (4)	28 Aug 2020 17:13:11
	(b) (4)	

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:02:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:13:11

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:02:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'Type II Diabetes Mellitus'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:13:11

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:02:15

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered '28-37'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:13:11

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:02:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'Other (OTHER)'	Karol Moore (b) (4)	28 Aug 2020 17:13:11
	(b) (4)	

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:02:15

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'units'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:13:11

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:02:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'as needed (PRN)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:13:11

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:02:15

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:13:11

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:02:15

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'Subcutaneous (SUBCUTANEOUS)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:13:11

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:02:15

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:13:11

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:02:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'un UNK 1990'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:13:11

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:02:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered '0'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:13:11

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:02:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:13:11

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:02:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:13:11

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:02:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:13:11

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:02:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Aug 2020 17:13:11

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:02:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Aug 2020 17:13:11

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:02:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Aug 2020 17:13:11

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:02:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SODIUM-GLUCOSE CO-TRANSPORTER 2 (SGLT2) INHIBITORS, PRODUCT: EMPAGLIFLOZIN, PRODUCTSYNONYM: JARDIANCE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 17:15:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 17:15:44
Data point term sent to Coder	System	28 Aug 2020 17:14:19
User entered 'jardiance'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:13:33

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:02:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:13:33

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:02:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'Type II Diabetes Mellitus'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:13:33

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:02:15

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered '25'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:13:33

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:02:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:13:33

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:02:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:13:33

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:02:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'once daily (QD)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:13:33

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:02:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:13:33

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:02:15

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:13:33

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:02:15

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:13:33

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'un UNK 2017'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:13:33

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:02:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered '0'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:13:33

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:02:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	17 Nov 2020 18:24:47
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:13:33

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:02:15

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered '05 Oct 2020' reason for change: New Information	(b) (4), (b) (6)	17 Nov 2020 18:24:47
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:13:33

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:02:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:43
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:13:33

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:02:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:43
User entered '1'	System	28 Aug 2020 17:13:33

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:02:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:43
User entered '1'	System	28 Aug 2020 17:13:33

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:02:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:43
User entered '804 (804)'	System	28 Aug 2020 17:13:33

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:02:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 20:49:47
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Aug 2020 17:15:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	28 Aug 2020 17:15:43
Data point term sent to Coder	System	28 Aug 2020 17:14:20
User entered 'metoprolol'	Karol Moore (b) (4)	28 Aug 2020 17:14:00
	(b) (4)	

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:02:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:14:00

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:02:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'hypertension'	Karol Moore (b) (4)	28 Aug 2020 17:14:00
	(b) (4)	

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:02:15

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered '50'	Karol Moore (b) (4)	28 Aug 2020 17:14:00
	(b) (4)	

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:02:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'mg (mg)'	Karol Moore (b) (4)	28 Aug 2020 17:14:00
	(b) (4)	

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:02:15

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:14:00

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:02:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'once daily (QD)'	Karol Moore (b) (4)	28 Aug 2020 17:14:00
	(b) (4)	

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:02:15

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered empty.	Karol Moore (b) (4)	28 Aug 2020 17:14:00
	(b) (4)	

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:02:15

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:14:00

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:02:15

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:14:00

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:02:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'un UNK 2015'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:14:00

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:02:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered '0'	Karol Moore (b) (4)	28 Aug 2020 17:14:00
	(b) (4)	

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:02:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:14:00

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:02:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:14:00

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:02:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:14:00

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:02:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 17:14:00

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:02:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 17:14:00

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:02:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Aug 2020 17:14:00

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:02:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 20:49:47
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Aug 2020 17:15:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Aug 2020 17:15:44
Data point term sent to Coder User entered 'losartan'	System	28 Aug 2020 17:14:20
	Karol Moore (b) (4)	28 Aug 2020 17:14:17
	(b) (4)	

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:02:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:14:17

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:02:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'hypertension'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:14:17

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:02:15

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered '25'	Karol Moore (b) (4)	28 Aug 2020 17:14:17
	(b) (4)	

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:02:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:14:17

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:02:15

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:14:17

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:02:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'once daily (QD)'	Karol Moore (b) (4)	28 Aug 2020 17:14:17
	(b) (4)	

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:02:15

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:14:17

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:02:15

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:14:17

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:02:15

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:14:17

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:02:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'un UNK 2015'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:14:17

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:02:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered '0'	Karol Moore (b) (4)	28 Aug 2020 17:14:17
	(b) (4)	

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:02:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:14:17

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:02:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:14:17

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:02:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:14:17

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:02:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 17:14:17

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:02:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 17:14:17

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:02:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Aug 2020 17:14:17

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:02:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 20:49:47
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Aug 2020 17:16:44
User coded data point as Term Coded data point by	Coder Import (b) (4)	28 Aug 2020 17:16:44
User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	28 Aug 2020 17:15:21
User entered 'furosemide'	Karol Moore (b) (4)	28 Aug 2020 17:14:38
	(b) (4)	

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:02:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:14:38

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:02:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'hypertension'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:14:38

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:02:15

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered '40'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:14:38

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:02:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:14:38

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:02:15

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:14:38

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:02:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'once daily (QD)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:14:38

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:02:15

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:14:38

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:02:15

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:14:38

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:02:15

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:14:38

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:02:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'un UNK 2015'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:14:38

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:02:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered '0'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:14:38

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:02:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:14:38

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:02:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:14:38

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:02:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:14:38

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:02:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 17:14:38

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:02:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 17:14:38

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:02:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Aug 2020 17:14:38

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:02:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 20:49:47
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)	28 Aug 2020 17:16:44
User coded data point as Term Coded data point by	Coder Import (b) (4)	28 Aug 2020 17:16:44
User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	28 Aug 2020 17:15:22
User entered 'spironolactone'	Karol Moore (b) (4)	28 Aug 2020 17:15:07
	(b) (4)	

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:02:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:15:07

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:02:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'hypertension'	Karol Moore (b) (4)	28 Aug 2020 17:15:07
	(b) (4)	

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:02:15

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered '12.5'	Karol Moore (b) (4)	28 Aug 2020 17:15:07
	(b) (4)	

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:02:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:15:07

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:02:15

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered empty.	Karol Moore (b) (4)	28 Aug 2020 17:15:07
	(b) (4)	

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:02:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'once daily (QD)'	Karol Moore (b) (4)	28 Aug 2020 17:15:07
	(b) (4)	

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:02:15

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered empty.	Karol Moore (b) (4)	28 Aug 2020 17:15:07
	(b) (4)	

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:02:15

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:15:07

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:02:15

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:15:07

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:02:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'un UNK 2015'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:15:07

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:02:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered '0'	Karol Moore (b) (4)	28 Aug 2020 17:15:07
	(b) (4)	

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:02:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:15:07

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:02:15

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:15:07

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:02:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'No (N)'	Karol Moore (b) (4)	28 Aug 2020 17:15:07
	(b) (4)	

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:02:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 17:15:07

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:02:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 17:15:07

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:02:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Aug 2020 17:15:07

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:02:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 20:49:47
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTI-PARKINSON DRUGS, ATC: DOPAMINERGIC AGENTS, ATC: DOPAMINE AGONISTS, PRODUCT: PRAMIPEXOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Aug 2020 17:17:44
User coded data point as Term Coded data point by	Coder Import (b) (4)	28 Aug 2020 17:17:44
User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	28 Aug 2020 17:16:27
User entered 'pramipexole'	Karol Moore (b) (4)	28 Aug 2020 17:15:31
	(b) (4)	

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:02:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:15:31

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:02:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'restless leg syndrome'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:15:31

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:02:15

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'I'	Karol Moore (b) (4)	28 Aug 2020 17:15:31
	(b) (4)	

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:02:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:15:31

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:02:15

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:15:31

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:02:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'once daily (QD)'	Karol Moore (b) (4)	28 Aug 2020 17:15:31
	(b) (4)	

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:02:15

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered empty.	Karol Moore (b) (4)	28 Aug 2020 17:15:31
	(b) (4)	

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:02:15

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'Oral (ORAL)'	Karol Moore (b) (4)	28 Aug 2020 17:15:31
	(b) (4)	

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:02:15

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered empty.	Karol Moore (b) (4)	28 Aug 2020 17:15:31
	(b) (4)	

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:02:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'un UNK 2010'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:15:31

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:02:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered '0'	Karol Moore (b) (4)	28 Aug 2020 17:15:31
	(b) (4)	

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:02:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:15:31

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:02:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:15:31

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:02:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:15:31

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:02:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 17:15:31

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:02:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 17:15:31

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:02:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Aug 2020 17:15:31

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:02:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: BACLOFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 17:17:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 17:17:45
Data point term sent to Coder	System	28 Aug 2020 17:16:27
User entered 'baclofen'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:16:13

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:02:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:16:13

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:02:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'restless leg syndrome'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:16:13

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:02:15

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered '5'	Karol Moore (b) (4)	28 Aug 2020 17:16:13
	(b) (4)	

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:02:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'mg (mg)'	Karol Moore (b) (4)	28 Aug 2020 17:16:13
	(b) (4)	

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:02:15

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:16:13

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:02:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'twice daily (BID)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:16:13

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:02:15

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered empty.	Karol Moore (b) (4)	28 Aug 2020 17:16:13
	(b) (4)	

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:02:15

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'Oral (ORAL)'	Karol Moore (b) (4)	28 Aug 2020 17:16:13
	(b) (4)	

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:02:15

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:16:13

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:02:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'un UNK 2010'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:16:13

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:02:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered '0'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:16:13

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:02:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:16:13

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:02:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:16:13

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:02:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:16:13

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:02:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	28 Aug 2020 17:16:13

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:02:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 17:16:13

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:02:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Aug 2020 17:16:13

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:02:15

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User closed query 'Per DM CLR: Please review ConMed #s 9 and 10, as both medication were noted as ongoing and have overlapping dates. Please reconcile dates and update so there is no overlap or delete duplicate record if applicable. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 11:04:50
Query 'Per DM CLR: Please review ConMed #s 9 and 10, as both medication were noted as ongoing and have overlapping dates. Please reconcile dates and update so there is no overlap or delete duplicate record if applicable. Otherwise, clarify. ' answered with 'correct as entered as different dosages bid and daily' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 22:13:33
User opened query 'Per DM CLR: Please review ConMed #s 9 and 10, as both medication were noted as ongoing and have overlapping dates. Please reconcile dates and update so there is no overlap or delete duplicate record if applicable. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 05:18:27
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: BACLOFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 17:17:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 17:17:45
Data point term sent to Coder	System	28 Aug 2020 17:17:29
User entered 'baclofen'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:16:43

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:02:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:16:43

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:02:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'restless leg syndrome'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:16:43

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:02:15

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered '10'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:16:43

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:02:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:16:43

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:02:15

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:16:43

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:02:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'once daily (QD)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:16:43

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:02:15

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:16:43

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:02:15

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:16:43

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:02:15

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:16:43

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:02:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'un UNK 2010'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:16:43

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:02:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered '0'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:16:43

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:02:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:16:43

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:02:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:16:43

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:02:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:16:43

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:02:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 17:16:43

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:02:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 17:16:43

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:02:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Aug 2020 17:16:43

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:02:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 20:49:47
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Aug 2020 17:20:50
User coded data point as Term Coded data point by	Coder Import (b) (4)	28 Aug 2020 17:20:50
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	28 Aug 2020 17:19:33
Data point term sent to Coder	System	28 Aug 2020 17:17:30
User entered 'rosuvastatin'	Karol Moore (b) (4)	28 Aug 2020 17:17:24
	(b) (4)	

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:02:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:17:24

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:02:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'hypercholesterolemia'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:17:24

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:02:15

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered '10'	Karol Moore (b) (4)	28 Aug 2020 17:17:24
	(b) (4)	

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:02:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:17:24

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:02:15

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:17:24

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:02:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'other (OTHER)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:17:24

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:02:15

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'three times a week'	Karol Moore (b) (4)	28 Aug 2020 17:17:24
	(b) (4)	

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:02:15

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User closed query 'Other, specify is provided, however Route of administration is not Other. Please correct.' (Site from System).	System	28 Aug 2020 17:19:27
User opened query 'Other, specify is provided, however Route of administration is not Other. Please correct.' (Site from System).	System	28 Aug 2020 17:17:24
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:17:24

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:02:15

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered empty; reason for change Data Entry Error	Karol Moore (b) (4)	28 Aug 2020 17:19:27
	(b) (4)	
User entered 'un'	Karol Moore (b) (4)	28 Aug 2020 17:17:24
	(b) (4)	

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:02:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'un UNK 2000'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:17:24

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:02:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered '0'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:17:24

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:02:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:17:24

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:02:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:17:24

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:02:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:17:24

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:02:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Aug 2020 17:17:24

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:02:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Aug 2020 17:17:24

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:02:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Aug 2020 17:17:24

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:02:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 20:49:47
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)	28 Aug 2020 17:19:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Aug 2020 17:19:47
Data point term sent to Coder	System	28 Aug 2020 17:18:31
User entered 'acetaminophen'	Karol Moore (b) (4)	28 Aug 2020 17:17:54
	(b) (4)	

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:02:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:17:54

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:02:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'osteoarthritis'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:17:54

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:02:15

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered '500'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:17:54

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:02:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:17:54

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:02:15

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:17:54

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:02:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'as needed (PRN)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:17:54

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:02:15

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered empty.	Karol Moore (b) (4)	28 Aug 2020 17:17:54
	(b) (4)	

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:02:15

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:17:54

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:02:15

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:17:54

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:02:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'un UNK 1998'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:17:54

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:02:15

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered '0'	Karol Moore (b) (4)	28 Aug 2020 17:17:54
	(b) (4)	

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:02:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'Yes (Y)'	Karol Moore (b) (4)	28 Aug 2020 17:17:54
	(b) (4)	

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:02:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:17:54

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:02:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'No (N)'	Karol Moore (b) (4)	28 Aug 2020 17:17:54
	(b) (4)	

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:02:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Aug 2020 17:17:54

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:02:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Aug 2020 17:17:54

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:02:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Aug 2020 17:17:54

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:02:15

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
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 17:20:51
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 17:20:51
Data point term sent to Coder	System	28 Aug 2020 17:19:32
User entered 'aspirin'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:18:33

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:02:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:18:33

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:02:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'cardiac prophylaxis'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:18:33

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:02:15

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered '81'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:18:33

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:02:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:18:33

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:02:15

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:18:33

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:02:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'other (OTHER)'	Karol Moore (b) (4)	28 Aug 2020 17:18:33
	(b) (4)	

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:02:15

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'three times per week'	Karol Moore (b) (4)	28 Aug 2020 17:18:33
	(b) (4)	

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:02:15

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:18:33

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:02:15

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:18:33

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:02:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'un UNK 1995'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:18:33

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:02:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered '0'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:18:33

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:02:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:18:33

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:02:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered empty.	Karol Moore (b) (4) (b) (4)	28 Aug 2020 17:18:33

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:02:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'No (N)'	Karol Moore (b) (4)	28 Aug 2020 17:18:33
	(b) (4)	

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:02:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Aug 2020 17:18:33

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:02:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Aug 2020 17:18:33

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:02:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Aug 2020 17:18:33

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:02:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:50
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: OTHER CEPHALOSPORINS AND PENEMS, PRODUCT: CEFTAROLINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 06:29:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 06:29:45
Data point term sent to Coder	System	25 Sep 2020 01:00:31
User entered 'ceftaroline'	(b) (4), (b) (6)	25 Sep 2020 01:00:07

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:02:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:50
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'No (N)'	(b) (4), (b) (6)	25 Sep 2020 01:00:07

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:02:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:50
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'Left great toe osteomyelitis'	(b) (4), (b) (6)	25 Sep 2020 01:00:07

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:02:15

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:50
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered '400'	(b) (4), (b) (6)	25 Sep 2020 01:00:07

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:02:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:50
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'mg (mg)'	(b) (4), (b) (6)	25 Sep 2020 01:00:07

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:02:15

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:50
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 01:00:07

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:02:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:50
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'twice daily (BID)'	(b) (4), (b) (6)	25 Sep 2020 01:00:07

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:02:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:50
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 01:00:07

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:02:15

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:50
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	25 Sep 2020 01:00:07

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:02:15

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:50
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 01:00:07

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:02:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:50
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User closed query 'Per DM CLR: The Con Med start date is prior to the start date of the AE. Please review and reconcile the Con Med and AE start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 11:06:52
Query 'Per DM CLR: The Con Med start date is prior to the start date of the AE. Please review and reconcile the Con Med and AE start dates as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 22:14:06
User entered '04 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 22:14:00
User opened query 'Per DM CLR: The Con Med start date is prior to the start date of the AE. Please review and reconcile the Con Med and AE start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 11:03:14
User entered '03 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 01:00:07

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:02:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:50
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 01:00:07

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:02:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:50
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 22:41:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 01:00:07

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:02:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:50
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered '15 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 22:41:08
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 01:00:07

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:02:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:50
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'No (N)'	(b) (4), (b) (6)	25 Sep 2020 01:00:07

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:02:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:50
User entered '2'	System	25 Sep 2020 01:00:07

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:02:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:50
User entered '1'	System	25 Sep 2020 01:00:07

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:02:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:50
User entered '804 (804)'	System	25 Sep 2020 01:00:07

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:02:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: ACICLOVIR, PRODUCTSYNONYM: ACYCLOVIR [ACICLOVIR] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 01:03:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 01:03:39
Data point term sent to Coder	System	25 Sep 2020 01:02:34
User entered 'acyclovir'	(b) (4), (b) (6)	25 Sep 2020 01:01:40

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:02:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'No (N)'	(b) (4), (b) (6)	25 Sep 2020 01:01:40

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:02:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'herpes zoster'	(b) (4), (b) (6)	25 Sep 2020 01:01:40

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:02:15

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered '800' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Sep 2020 01:03:33
User entered '200'	(b) (4), (b) (6)	25 Sep 2020 01:01:40

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:02:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'mg (mg)'	(b) (4), (b) (6)	25 Sep 2020 01:01:40

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:02:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 01:01:40

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:02:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'other (OTHER)'	(b) (4), (b) (6)	25 Sep 2020 01:01:40

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:02:15

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered '5 x day'	(b) (4), (b) (6)	25 Sep 2020 01:01:40

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:02:15

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	25 Sep 2020 01:01:40

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:02:15

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 01:01:40

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:02:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered '04 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 01:01:40

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:02:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 01:01:40

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:02:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'No (N)'	(b) (4), (b) (6)	25 Sep 2020 01:01:40

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:02:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered '08 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 01:01:40

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:02:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:53
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'No (N)'	(b) (4), (b) (6)	25 Sep 2020 01:01:40

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:02:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:53
User entered empty.	System	25 Sep 2020 01:01:40

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:02:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:53
User entered empty.	System	25 Sep 2020 01:01:40

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:02:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:53
User entered empty.	System	25 Sep 2020 01:01:40

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:02:15

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:56
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, WEAK (GROUP I), PRODUCT: HYDROCORTISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 06:23:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 06:23:52
Data point term sent to Coder	System	25 Sep 2020 01:03:34
User entered 'hydrocortisone 1%'	(b) (4), (b) (6)	25 Sep 2020 01:02:35

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:02:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:56
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'No (N)'	(b) (4), (b) (6)	25 Sep 2020 01:02:35

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:02:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:56
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'herpes zoster'	(b) (4), (b) (6)	25 Sep 2020 01:02:35

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:02:15

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:56
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'I'	(b) (4), (b) (6)	25 Sep 2020 01:02:35

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:02:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:56
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'Other (OTHER)'	(b) (4), (b) (6)	25 Sep 2020 01:02:35

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:02:15

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:56
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'application'	(b) (4), (b) (6)	25 Sep 2020 01:02:35

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:02:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:56
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'as needed (PRN)'	(b) (4), (b) (6)	25 Sep 2020 01:02:35

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:02:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:56
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 01:02:35

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:02:15

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:56
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'Topical (TOPICAL)'	(b) (4), (b) (6)	25 Sep 2020 01:02:35

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:02:15

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:56
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 01:02:35

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:02:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:56
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	25 Sep 2020 01:02:50
User entered '10 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Sep 2020 01:02:50
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	25 Sep 2020 01:02:35
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 01:02:35

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:02:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:56
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 01:02:35

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:02:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:56
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User closed query 'Per source medication has stop date. Please verify and update as needed. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:27:22
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:27:20
Query 'Per source medication has stop date. Please verify and update as needed. ' answered with 'updated' (Site from CRA).	Monica Atwood (b) (4) (b) (4)	24 Nov 2020 22:19:24
User entered 'No (N)' reason for change: Data Entry Error	Monica Atwood (b) (4) (b) (4)	24 Nov 2020 22:19:14
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 20:49:56
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:49:47
User opened query 'Per source medication has stop date. Please verify and update as needed. ' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 20:48:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 01:02:35

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:02:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:56
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:27:18
User entered '24 Sep 2020' reason for change: Data Entry Error	Monica Atwood (b) (4)	24 Nov 2020 22:19:14
DataPoint Un-verified.	(b) (4)	24 Nov 2020 20:49:57
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 01:02:35

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:02:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:56
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Sep 2020 01:02:39
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Sep 2020 01:02:39
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Sep 2020 01:02:39
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Sep 2020 01:02:35
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 01:02:35

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:02:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:56
User entered empty.	System	25 Sep 2020 01:02:35

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:02:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:56
User entered empty.	System	25 Sep 2020 01:02:35

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:02:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:56
User entered empty.	System	25 Sep 2020 01:02:35

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:02:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:49:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES, PRODUCT: DULAGLUTIDE, PRODUCTSYNONYM: TRULICITY - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 01:19:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 01:19:46
Data point term sent to Coder	System	25 Sep 2020 01:18:45
User entered 'trulicity'	(b) (4), (b) (6)	25 Sep 2020 01:18:36

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:02:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:49:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'No (N)'	(b) (4), (b) (6)	25 Sep 2020 01:18:36

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:02:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:49:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'Diabetes mellitus type II'	(b) (4), (b) (6)	25 Sep 2020 01:18:36

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:02:15

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:49:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered '1.5'	(b) (4), (b) (6)	25 Sep 2020 01:18:36

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:02:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:49:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'mg (mg)'	(b) (4), (b) (6)	25 Sep 2020 01:18:36

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:02:15

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:49:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 01:18:36

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:02:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:49:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'other (OTHER)'	(b) (4), (b) (6)	25 Sep 2020 01:18:36

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:02:15

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:49:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'weekly'	(b) (4), (b) (6)	25 Sep 2020 01:18:36

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:02:15

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:49:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4), (b) (6)	25 Sep 2020 01:18:36

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:02:15

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:49:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 01:18:36

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:02:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:49:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	07 Oct 2020 00:28:04
User entered 'UN UNK 2017' reason for change:	Karol Moore (b) (4)	07 Oct 2020 00:28:04
Data Entry Error	(b) (4)	
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	25 Sep 2020 01:18:36
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 01:18:36

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:02:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:49:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 01:18:36

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:02:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:49:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 22:39:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 01:18:36

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:02:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:49:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered '01 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 22:39:51
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 01:18:36

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:02:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:49:02
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'No (N)'	(b) (4), (b) (6)	25 Sep 2020 01:18:36

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:02:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:49:02
User entered empty.	System	25 Sep 2020 01:18:36

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:02:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:49:02
User entered empty.	System	25 Sep 2020 01:18:36

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:02:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:49:02
User entered empty.	System	25 Sep 2020 01:18:36

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:02:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
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: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 01:20:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 01:20:38
Data point term sent to Coder	System	25 Sep 2020 01:19:47
User entered 'vitamin D3'	(b) (4), (b) (6)	25 Sep 2020 01:19:46

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:02:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'No (N)'	(b) (4), (b) (6)	25 Sep 2020 01:19:46

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:02:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'health maintenance'	(b) (4), (b) (6)	25 Sep 2020 01:19:46

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:02:15

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered '1000'	(b) (4), (b) (6)	25 Sep 2020 01:19:46

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:02:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'Other (OTHER)'	(b) (4), (b) (6)	25 Sep 2020 01:19:46

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:02:15

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'units'	(b) (4), (b) (6)	25 Sep 2020 01:19:46

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:02:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'once daily (QD)'	(b) (4), (b) (6)	25 Sep 2020 01:19:46

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:02:15

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 01:19:46

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:02:15

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	25 Sep 2020 01:19:46

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:02:15

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 01:19:46

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:02:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	25 Sep 2020 01:20:38
User entered 'un UNK 2017' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Sep 2020 01:20:38
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	25 Sep 2020 01:19:46
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 01:19:46

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:02:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 01:19:46

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:02:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 01:19:46

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:02:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 01:19:46

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:02:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'No (N)'	(b) (4), (b) (6)	25 Sep 2020 01:19:46

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:02:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 01:19:46

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:02:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 01:19:46

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:02:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Sep 2020 01:19:46

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:02:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:49:07
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
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)	12 Oct 2020 15:39:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Oct 2020 15:39:21
Data point term sent to Coder	System	12 Oct 2020 15:38:04
User entered 'SEASONAL INFLUENZA VACCINE'	Monica Atwood (b) (4) (b) (4)	12 Oct 2020 15:37:03
DataPoint activated with code reason code Data required.	Monica Atwood (b) (4) (b) (4)	12 Oct 2020 15:36:06
DataPoint inactivated with code reason code Data not required.	Karol Moore (b) (4) (b) (4)	07 Oct 2020 00:28:39

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:02:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:49:07
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'Yes (Y)'	Monica Atwood (b) (4)	12 Oct 2020 15:37:03
DataPoint activated with code reason code Data required.	(b) (4) Monica Atwood (b) (4)	12 Oct 2020 15:36:06
DataPoint inactivated with code reason code Data not required.	Karol Moore (b) (4) (b) (4)	07 Oct 2020 00:28:39

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:02:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:49:07
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'SEASONAL INFLUENZA PROPHYLAXIS'	Monica Atwood (b) (4)	12 Oct 2020 15:37:03
DataPoint activated with code reason code Data required.	(b) (4) Monica Atwood (b) (4)	12 Oct 2020 15:36:06
DataPoint inactivated with code reason code Data not required.	Karol Moore (b) (4) (b) (4)	07 Oct 2020 00:28:39

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:02:15

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:49:07
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 19:13:30
User entered '0.5' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Dec 2020 19:13:30
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered '1'	Monica Atwood (b) (4) (b) (4)	12 Oct 2020 15:37:03
DataPoint activated with code reason code Data required.	Monica Atwood (b) (4) (b) (4)	12 Oct 2020 15:36:06
DataPoint inactivated with code reason code Data not required.	Karol Moore (b) (4) (b) (4)	07 Oct 2020 00:28:39

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:02:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:49:07
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 19:13:30
User entered 'mL (mL)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Dec 2020 19:13:30
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'Other (OTHER)'	Monica Atwood (b) (4) (b) (4)	12 Oct 2020 15:37:03
DataPoint activated with code reason code Data required.	Monica Atwood (b) (4) (b) (4)	12 Oct 2020 15:36:06
DataPoint inactivated with code reason code Data not required.	Karol Moore (b) (4) (b) (4)	07 Oct 2020 00:28:39

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:02:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:49:07
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 19:13:30
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	18 Dec 2020 19:13:30
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'INJECTION'	Monica Atwood (b) (4) (b) (4)	12 Oct 2020 15:37:03
DataPoint activated with code reason code Data required.	Monica Atwood (b) (4) (b) (4)	12 Oct 2020 15:36:06
DataPoint inactivated with code reason code Data not required.	Karol Moore (b) (4) (b) (4)	07 Oct 2020 00:28:39

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:02:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:49:07
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'once (ONCE)'	Monica Atwood (b) (4)	12 Oct 2020 15:37:03
DataPoint activated with code reason code Data required.	(b) (4) Monica Atwood (b) (4)	12 Oct 2020 15:36:06
DataPoint inactivated with code reason code Data not required.	(b) (4) Karol Moore (b) (4)	07 Oct 2020 00:28:39

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:02:15

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:49:07
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered empty.	Monica Atwood (b) (4)	12 Oct 2020 15:37:03
DataPoint activated with code reason code Data required.	(b) (4) Monica Atwood (b) (4)	12 Oct 2020 15:36:06
DataPoint inactivated with code reason code Data not required.	(b) (4) Karol Moore (b) (4)	07 Oct 2020 00:28:39

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:02:15

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:49:07
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'Intramuscular (INTRAMUSCULAR)'	Monica Atwood (b) (4)	12 Oct 2020 15:37:03
DataPoint activated with code reason code Data required.	(b) (4) Monica Atwood (b) (4)	12 Oct 2020 15:36:06
DataPoint inactivated with code reason code Data not required.	(b) (4) Karol Moore (b) (4)	07 Oct 2020 00:28:39

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:02:15

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:49:07
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered empty.	Monica Atwood (b) (4)	12 Oct 2020 15:37:03
DataPoint activated with code reason code Data required.	(b) (4) Monica Atwood (b) (4)	12 Oct 2020 15:36:06
DataPoint inactivated with code reason code Data not required.	(b) (4) Karol Moore (b) (4)	07 Oct 2020 00:28:39

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:02:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:49:07
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered '3 Oct 2020'	Monica Atwood (b) (4)	12 Oct 2020 15:37:03
DataPoint activated with code reason code Data required.	(b) (4) Monica Atwood (b) (4)	12 Oct 2020 15:36:06
DataPoint inactivated with code reason code Data not required.	(b) (4) Karol Moore (b) (4)	07 Oct 2020 00:28:39

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:02:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:49:07
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered '0'	Monica Atwood (b) (4)	12 Oct 2020 15:37:03
DataPoint activated with code reason code Data required.	(b) (4) Monica Atwood (b) (4)	12 Oct 2020 15:36:06
DataPoint inactivated with code reason code Data not required.	Karol Moore (b) (4) (b) (4)	07 Oct 2020 00:28:39

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:02:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:49:07
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'No (N)'	Monica Atwood (b) (4)	12 Oct 2020 15:37:03
DataPoint activated with code reason code Data required.	(b) (4) Monica Atwood (b) (4)	12 Oct 2020 15:36:06
DataPoint inactivated with code reason code Data not required.	(b) (4) Karol Moore (b) (4)	07 Oct 2020 00:28:39

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:02:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:49:07
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered '3 Oct 2020'	Monica Atwood (b) (4)	12 Oct 2020 15:37:03
DataPoint activated with code reason code Data required.	(b) (4) Monica Atwood (b) (4)	12 Oct 2020 15:36:06
DataPoint inactivated with code reason code Data not required.	(b) (4) Karol Moore (b) (4)	07 Oct 2020 00:28:39

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:02:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:49:07
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'No (N)'	Monica Atwood (b) (4)	12 Oct 2020 15:37:03
DataPoint activated with code reason code Data required.	(b) (4) Monica Atwood (b) (4)	12 Oct 2020 15:36:06
DataPoint inactivated with code reason code Data not required.	Karol Moore (b) (4) (b) (4)	07 Oct 2020 00:28:39

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:02:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:49:07
User entered empty.	System	12 Oct 2020 15:37:03
DataPoint activated with code reason code Data required.	Monica Atwood (b) (4)	12 Oct 2020 15:36:06
DataPoint inactivated with code reason code Data not required.	(b) (4)	07 Oct 2020 00:28:39
	Karol Moore (b) (4)	
	(b) (4)	

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:02:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:49:07
User entered empty.	System	12 Oct 2020 15:37:03
DataPoint activated with code reason code Data required.	Monica Atwood (b) (4)	12 Oct 2020 15:36:06
DataPoint inactivated with code reason code Data not required.	(b) (4)	07 Oct 2020 00:28:39

US3312212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:02:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:49:07
User entered empty.	System	12 Oct 2020 15:37:03
DataPoint activated with code reason code Data required.	Monica Atwood (b) (4)	12 Oct 2020 15:36:06
DataPoint inactivated with code reason code Data not required.	(b) (4)	07 Oct 2020 00:28:39
	Karol Moore (b) (4)	
	(b) (4)	

US3312212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:02:15

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:25:51
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 01:20:56

US3312212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:02:15

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 20:50:15
User entered '04 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 01:21:16

US3312212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:02:15

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:50:15
User entered 'left great toe amputation'	(b) (4), (b) (6)	25 Sep 2020 01:21:16

US3312212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:02:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:50:15
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	25 Sep 2020 01:21:16

US3312212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:02:15

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 20:50:15
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 01:21:16

US3312212

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:02:15

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:51:03
User closed query 'Per CDM-Date of dosing discontinuation is recorded as 18 SEP 2020 ,however SAE #1 end date is recorded as 16 OCT 2020.Kindly consider to reconcile and confirm to update correct date of dosing discontinuation else please clarify. Thank you.' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Carlos Fierro (b) (4)	08 Apr 2021 06:24:45 07 Apr 2021 18:09:29
Query 'Per CDM-Date of dosing discontinuation is recorded as 18 SEP 2020 ,however SAE #1 end date is recorded as 16 OCT 2020.Kindly consider to reconcile and confirm to update correct date of dosing discontinuation else please clarify. Thank you.' answered with 'CORRECT AS ENTERED. SAE HAD NOT RESOLVED IN TIME FOR D29 VISIT ON 18SEP2020, THEREFORE DOSING DISCONTINUED ON 18SEP2020' (Site from DM). User opened query 'Per CDM-Date of dosing discontinuation is recorded as 18 SEP 2020 ,however SAE #1 end date is recorded as 16 OCT 2020.Kindly consider to reconcile and confirm to update correct date of dosing discontinuation else please clarify. Thank you.' (Site from DM).	Karol Moore (b) (4) (b) (4) (b) (4), (b) (6)	07 Apr 2021 14:58:20 17 Mar 2021 12:36:36
Query 'Per CDM-Date of dosing discontinuation is recorded as 18 SEP 2020 ,however SAE #1 end date is recorded as 16 OCT 2021.Kindly consider to reconcile and confirm to update correct date of dosing discntinuation else please clarify.Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 12:36:11
User opened query 'Per CDM-Date of dosing discontinuation is recorded as 18 SEP 2020 ,however SAE #1 end date is recorded as 16 OCT 2021.Kindly consider to reconcile and confirm to update correct date of dosing discntinuation else please clarify.Thank you.' (Site from DM). User entered '18 Sep 2020'	(b) (4), (b) (6) (b) (4), (b) (6)	17 Mar 2021 12:35:03 25 Sep 2020 01:25:39

US3312212

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:02:15

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:51:03
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:29
User closed query 'Per CDM: Primary reason for dosing discontinuation is recorded as 'SAE',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 14:40:12
Query 'Per CDM: Primary reason for dosing discontinuation is recorded as 'SAE',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 DC study, just IP' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 22:43:20
User opened query 'Per CDM: Primary reason for dosing discontinuation is recorded as 'SAE',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)	30 Sep 2020 09:36:13
User entered 'SAE (specify) (SAE)'	(b) (4), (b) (6)	25 Sep 2020 01:25:39

US3312212

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:02:15

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 11:51:03
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 18:09:29
User closed query 'Per CDM Re-query: thank you for teh update however per CCGs please remove details.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 08:40:43
Query 'Per CDM Re-query: thank you for teh update however per CCGs please remove details.' answered with 'UPDATED' (Site from DM).	Karol Moore (b) (4) (b) (4)	23 Nov 2020 18:34:05
User entered 'SAE#1' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	23 Nov 2020 18:34:01
User opened query 'Per CDM Re-query: thank you for teh update however per CCGs please remove details.' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 22:39:36
User closed query 'Per CDM: please record SAE record number (i.e. SAE #1, etc.) instead of details' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 22:39:36
Query 'Per CDM: please record SAE record number (i.e. SAE #1, etc.) instead of details' answered with 'UPDATED' (Site from DM).	Monica Atwood (b) (4) (b) (4)	20 Nov 2020 16:19:14
User entered 'SAE#1- (NOT RELATED) OF LEFT GREAT TOE OSTEOMYELITIS' reason for change: Data Entry Error	Monica Atwood (b) (4) (b) (4)	20 Nov 2020 16:18:52
User opened query 'Per CDM: please record SAE record number (i.e. SAE #1, etc.) instead of details' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 14:57:51
User entered 'SAE (not related) of left great toe osteomyelitis'	(b) (4), (b) (6)	25 Sep 2020 01:25:39

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:52:51
User entered		
'USA-US300-2020-MRNA-1273-P301000002'	System	07 Sep 2020 20:51:44

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

Serious

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:52:51
User entered 'Yes (Y)'	System	07 Sep 2020 20:51:44

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:52:51
User entered 'No (N)'	System	07 Sep 2020 20:51:44

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:52:51
User entered 'No (N)'	System	07 Sep 2020 20:51:44

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:52:51
User entered 'Yes (Y)'	System	07 Sep 2020 20:51:44

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:52:51
User entered 'No (N)'	System	07 Sep 2020 20:51:44

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:52:51
User entered 'No (N)'	System	07 Sep 2020 20:51:44

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:52:51
User entered 'No (N)'	System	07 Sep 2020 20:51:44

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:54:34
Un-reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 13:27:13
User entered 'Carlos' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 13:27:13
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 17:09:38
Amendment Manager: User entered empty.	System	14 Sep 2020 22:05:45
User entered 'Carlos'	(b) (4), (b) (6)	09 Sep 2020 00:08:03

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:54:34
Un-reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 13:27:13
User entered 'Fierro' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 13:27:13
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 17:09:38
Amendment Manager: User entered empty.	System	14 Sep 2020 22:05:45
User entered 'Fierro'	(b) (4), (b) (6)	09 Sep 2020 00:08:03

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:54:34
Un-reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 13:27:13
User entered '16300 College Blvd' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 13:27:13
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 17:09:38
Amendment Manager: User entered empty.	System	14 Sep 2020 22:05:45
User entered '16300 College Blvd'	(b) (4), (b) (6)	09 Sep 2020 00:08:03

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:54:34
User entered 'Shawnee'	System	25 Sep 2020 13:52:03
Un-reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 13:27:13
User entered 'Lenexa' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 13:27:13
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 17:09:38
Amendment Manager: User entered empty.	System	14 Sep 2020 22:05:45
User entered 'Lenexa'	(b) (4), (b) (6)	09 Sep 2020 00:08:03

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:54:34
User entered 'KS'	System	25 Sep 2020 13:52:03
Un-reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 13:27:13
User entered 'Kansas' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 13:27:13
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 17:09:38
Amendment Manager: User entered empty.	System	14 Sep 2020 22:05:45
User entered 'KS'	(b) (4), (b) (6)	09 Sep 2020 00:08:03

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:54:34
Un-reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 13:27:13
User entered '66219' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 13:27:13
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 17:09:38
Amendment Manager: User entered empty.	System	14 Sep 2020 22:05:45
User entered '66219'	(b) (4), (b) (6)	09 Sep 2020 00:08:03

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:56:00
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 02:00:46
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 17:09:38
User entered 'US' (non-conformant).	System	07 Sep 2020 20:52:56

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	25 Nov 2020 17:31:59
User entered '6'	System	10 Nov 2020 18:09:06
User entered '5'	System	10 Nov 2020 16:36:52
User entered '4'	System	07 Oct 2020 14:54:48
User entered '3'	System	25 Sep 2020 13:52:03
User entered '2'	System	17 Sep 2020 17:09:58
User entered '1'	System	07 Sep 2020 20:52:56

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:52:51
User entered		
'USA-US300-2020-MRNA-1273-P301000002'	System	07 Sep 2020 20:51:44

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

Serious

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:52:51
User entered 'Yes (Y)'	System	07 Sep 2020 20:51:44

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:52:51
User entered 'No (N)'	System	07 Sep 2020 20:51:44

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:52:51
User entered 'No (N)'	System	07 Sep 2020 20:51:44

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:52:51
User entered 'Yes (Y)'	System	07 Sep 2020 20:51:44

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:52:51
User entered 'No (N)'	System	07 Sep 2020 20:51:44

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:52:51
User entered 'No (N)'	System	07 Sep 2020 20:51:44

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:52:51
User entered 'No (N)'	System	07 Sep 2020 20:51:44

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:54:34
Un-reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 13:27:13
User entered 'Carlos' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 13:27:13
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 17:09:38
Amendment Manager: User entered empty.	System	14 Sep 2020 22:05:45
User entered 'Carlos'	(b) (4), (b) (6)	09 Sep 2020 00:08:03

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:54:34
Un-reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 13:27:13
User entered 'Fierro' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 13:27:13
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 17:09:38
Amendment Manager: User entered empty.	System	14 Sep 2020 22:05:45
User entered 'Fierro'	(b) (4), (b) (6)	09 Sep 2020 00:08:03

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:54:34
Un-reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 13:27:13
User entered '16300 College Blvd' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 13:27:13
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 17:09:38
Amendment Manager: User entered empty.	System	14 Sep 2020 22:05:45
User entered '16300 College Blvd'	(b) (4), (b) (6)	09 Sep 2020 00:08:03

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:54:34
User entered 'Shawnee'	System	25 Sep 2020 13:52:03
Un-reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 13:27:13
User entered 'Lenexa' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 13:27:13
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 17:09:38
Amendment Manager: User entered empty.	System	14 Sep 2020 22:05:45
User entered 'Lenexa'	(b) (4), (b) (6)	09 Sep 2020 00:08:03

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:54:34
User entered 'KS'	System	25 Sep 2020 13:52:03
Un-reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 13:27:13
User entered 'Kansas' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 13:27:13
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 17:09:38
Amendment Manager: User entered empty.	System	14 Sep 2020 22:05:45
User entered 'KS'	(b) (4), (b) (6)	09 Sep 2020 00:08:03

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:54:34
Un-reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 13:27:13
User entered '66219' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 13:27:13
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 17:09:38
Amendment Manager: User entered empty.	System	14 Sep 2020 22:05:45
User entered '66219'	(b) (4), (b) (6)	09 Sep 2020 00:08:03

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:56:00
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 02:00:46
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 17:09:38
User entered 'US' (non-conformant).	System	07 Sep 2020 20:52:56

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	25 Nov 2020 17:31:59
User entered '6'	System	10 Nov 2020 18:09:06
User entered '5'	System	10 Nov 2020 16:36:52
User entered '4'	System	07 Oct 2020 14:54:48
User entered '3'	System	25 Sep 2020 13:52:03
User entered '2'	System	17 Sep 2020 17:09:58
User entered '1'	System	07 Sep 2020 20:52:56

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:02:15

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:56:00
User entered '07/Sep/2020 16:52'	System	07 Sep 2020 20:52:56

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:02:15

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 17:09:38
User entered 'I'	(b) (4), (b) (6)	07 Sep 2020 20:52:56

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:52:51
User entered		
'USA-US300-2020-MRNA-1273-P301000002'	System	07 Sep 2020 20:51:44

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

Serious

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:52:51
User entered 'Yes (Y)'	System	07 Sep 2020 20:51:44

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:52:51
User entered 'No (N)'	System	07 Sep 2020 20:51:44

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:52:51
User entered 'No (N)'	System	07 Sep 2020 20:51:44

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:52:51
User entered 'Yes (Y)'	System	07 Sep 2020 20:51:44

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:52:51
User entered 'No (N)'	System	07 Sep 2020 20:51:44

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:52:51
User entered 'No (N)'	System	07 Sep 2020 20:51:44

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:52:51
User entered 'No (N)'	System	07 Sep 2020 20:51:44

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:54:34
Un-reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 13:27:13
User entered 'Carlos' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 13:27:13
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 17:09:38
Amendment Manager: User entered empty.	System	14 Sep 2020 22:05:45
User entered 'Carlos'	(b) (4), (b) (6)	09 Sep 2020 00:08:03

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:54:34
Un-reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 13:27:13
User entered 'Fierro' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 13:27:13
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 17:09:38
Amendment Manager: User entered empty.	System	14 Sep 2020 22:05:45
User entered 'Fierro'	(b) (4), (b) (6)	09 Sep 2020 00:08:03

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:54:34
Un-reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 13:27:13
User entered '16300 College Blvd' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 13:27:13
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 17:09:38
Amendment Manager: User entered empty.	System	14 Sep 2020 22:05:45
User entered '16300 College Blvd'	(b) (4), (b) (6)	09 Sep 2020 00:08:03

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:54:34
User entered 'Shawnee'	System	25 Sep 2020 13:52:03
Un-reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 13:27:13
User entered 'Lenexa' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 13:27:13
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 17:09:38
Amendment Manager: User entered empty.	System	14 Sep 2020 22:05:45
User entered 'Lenexa'	(b) (4), (b) (6)	09 Sep 2020 00:08:03

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:54:34
User entered 'KS'	System	25 Sep 2020 13:52:03
Un-reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 13:27:13
User entered 'Kansas' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 13:27:13
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 17:09:38
Amendment Manager: User entered empty.	System	14 Sep 2020 22:05:45
User entered 'KS'	(b) (4), (b) (6)	09 Sep 2020 00:08:03

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:54:34
Un-reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 13:27:13
User entered '66219' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 13:27:13
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 17:09:38
Amendment Manager: User entered empty.	System	14 Sep 2020 22:05:45
User entered '66219'	(b) (4), (b) (6)	09 Sep 2020 00:08:03

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:56:00
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 02:00:46
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 17:09:38
User entered 'US' (non-conformant).	System	07 Sep 2020 20:52:56

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	25 Nov 2020 17:31:59
User entered '6'	System	10 Nov 2020 18:09:06
User entered '5'	System	10 Nov 2020 16:36:52
User entered '4'	System	07 Oct 2020 14:54:48
User entered '3'	System	25 Sep 2020 13:52:03
User entered '2'	System	17 Sep 2020 17:09:58
User entered '1'	System	07 Sep 2020 20:52:56

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:02:15

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:56:00
User entered '17/Sep/2020 13:09'	System	17 Sep 2020 17:09:58

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:02:15

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:54:34
User entered 'I'	(b) (4), (b) (6)	17 Sep 2020 17:09:58

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:52:51
User entered		
'USA-US300-2020-MRNA-1273-P301000002'	System	07 Sep 2020 20:51:44

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

Serious

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:52:51
User entered 'Yes (Y)'	System	07 Sep 2020 20:51:44

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:52:51
User entered 'No (N)'	System	07 Sep 2020 20:51:44

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:52:51
User entered 'No (N)'	System	07 Sep 2020 20:51:44

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:52:51
User entered 'Yes (Y)'	System	07 Sep 2020 20:51:44

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:52:51
User entered 'No (N)'	System	07 Sep 2020 20:51:44

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:52:51
User entered 'No (N)'	System	07 Sep 2020 20:51:44

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:52:51
User entered 'No (N)'	System	07 Sep 2020 20:51:44

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:54:34
Un-reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 13:27:13
User entered 'Carlos' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 13:27:13
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 17:09:38
Amendment Manager: User entered empty.	System	14 Sep 2020 22:05:45
User entered 'Carlos'	(b) (4), (b) (6)	09 Sep 2020 00:08:03

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:54:34
Un-reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 13:27:13
User entered 'Fierro' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 13:27:13
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 17:09:38
Amendment Manager: User entered empty.	System	14 Sep 2020 22:05:45
User entered 'Fierro'	(b) (4), (b) (6)	09 Sep 2020 00:08:03

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:54:34
Un-reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 13:27:13
User entered '16300 College Blvd' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 13:27:13
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 17:09:38
Amendment Manager: User entered empty.	System	14 Sep 2020 22:05:45
User entered '16300 College Blvd'	(b) (4), (b) (6)	09 Sep 2020 00:08:03

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:54:34
User entered 'Shawnee'	System	25 Sep 2020 13:52:03
Un-reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 13:27:13
User entered 'Lenexa' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 13:27:13
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 17:09:38
Amendment Manager: User entered empty.	System	14 Sep 2020 22:05:45
User entered 'Lenexa'	(b) (4), (b) (6)	09 Sep 2020 00:08:03

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:54:34
User entered 'KS'	System	25 Sep 2020 13:52:03
Un-reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 13:27:13
User entered 'Kansas' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 13:27:13
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 17:09:38
Amendment Manager: User entered empty.	System	14 Sep 2020 22:05:45
User entered 'KS'	(b) (4), (b) (6)	09 Sep 2020 00:08:03

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:54:34
Un-reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 13:27:13
User entered '66219' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 13:27:13
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 17:09:38
Amendment Manager: User entered empty.	System	14 Sep 2020 22:05:45
User entered '66219'	(b) (4), (b) (6)	09 Sep 2020 00:08:03

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:56:00
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 02:00:46
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 17:09:38
User entered 'US' (non-conformant).	System	07 Sep 2020 20:52:56

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	25 Nov 2020 17:31:59
User entered '6'	System	10 Nov 2020 18:09:06
User entered '5'	System	10 Nov 2020 16:36:52
User entered '4'	System	07 Oct 2020 14:54:48
User entered '3'	System	25 Sep 2020 13:52:03
User entered '2'	System	17 Sep 2020 17:09:58
User entered '1'	System	07 Sep 2020 20:52:56

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:02:15

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:56:00
User entered '24/Sep/2020 08:40'	(b) (4), (b) (6)	25 Sep 2020 00:50:05

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:02:15

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:54:34
User entered 'I'	(b) (4), (b) (6)	25 Sep 2020 13:52:03

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:52:51
User entered		
'USA-US300-2020-MRNA-1273-P301000002'	System	07 Sep 2020 20:51:44

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

Serious

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:52:51
User entered 'Yes (Y)'	System	07 Sep 2020 20:51:44

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:52:51
User entered 'No (N)'	System	07 Sep 2020 20:51:44

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:52:51
User entered 'No (N)'	System	07 Sep 2020 20:51:44

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:52:51
User entered 'Yes (Y)'	System	07 Sep 2020 20:51:44

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:52:51
User entered 'No (N)'	System	07 Sep 2020 20:51:44

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:52:51
User entered 'No (N)'	System	07 Sep 2020 20:51:44

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:52:51
User entered 'No (N)'	System	07 Sep 2020 20:51:44

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:54:34
Un-reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 13:27:13
User entered 'Carlos' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 13:27:13
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 17:09:38
Amendment Manager: User entered empty.	System	14 Sep 2020 22:05:45
User entered 'Carlos'	(b) (4), (b) (6)	09 Sep 2020 00:08:03

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:54:34
Un-reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 13:27:13
User entered 'Fierro' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 13:27:13
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 17:09:38
Amendment Manager: User entered empty.	System	14 Sep 2020 22:05:45
User entered 'Fierro'	(b) (4), (b) (6)	09 Sep 2020 00:08:03

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:54:34
Un-reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 13:27:13
User entered '16300 College Blvd' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 13:27:13
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 17:09:38
Amendment Manager: User entered empty.	System	14 Sep 2020 22:05:45
User entered '16300 College Blvd'	(b) (4), (b) (6)	09 Sep 2020 00:08:03

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:54:34
User entered 'Shawnee'	System	25 Sep 2020 13:52:03
Un-reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 13:27:13
User entered 'Lenexa' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 13:27:13
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 17:09:38
Amendment Manager: User entered empty.	System	14 Sep 2020 22:05:45
User entered 'Lenexa'	(b) (4), (b) (6)	09 Sep 2020 00:08:03

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:54:34
User entered 'KS'	System	25 Sep 2020 13:52:03
Un-reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 13:27:13
User entered 'Kansas' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 13:27:13
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 17:09:38
Amendment Manager: User entered empty.	System	14 Sep 2020 22:05:45
User entered 'KS'	(b) (4), (b) (6)	09 Sep 2020 00:08:03

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:54:34
Un-reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 13:27:13
User entered '66219' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 13:27:13
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 17:09:38
Amendment Manager: User entered empty.	System	14 Sep 2020 22:05:45
User entered '66219'	(b) (4), (b) (6)	09 Sep 2020 00:08:03

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:56:00
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 02:00:46
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 17:09:38
User entered 'US' (non-conformant).	System	07 Sep 2020 20:52:56

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	25 Nov 2020 17:31:59
User entered '6'	System	10 Nov 2020 18:09:06
User entered '5'	System	10 Nov 2020 16:36:52
User entered '4'	System	07 Oct 2020 14:54:48
User entered '3'	System	25 Sep 2020 13:52:03
User entered '2'	System	17 Sep 2020 17:09:58
User entered '1'	System	07 Sep 2020 20:52:56

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:02:15

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:56:00
User entered '07/Oct/2020 14:54'	System	07 Oct 2020 14:54:48

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:02:15

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:36:41
User entered 'I'	(b) (4), (b) (6)	07 Oct 2020 14:54:48

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:52:51
User entered		
'USA-US300-2020-MRNA-1273-P301000002'	System	07 Sep 2020 20:51:44

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

Serious

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:52:51
User entered 'Yes (Y)'	System	07 Sep 2020 20:51:44

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:52:51
User entered 'No (N)'	System	07 Sep 2020 20:51:44

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:52:51
User entered 'No (N)'	System	07 Sep 2020 20:51:44

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:52:51
User entered 'Yes (Y)'	System	07 Sep 2020 20:51:44

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:52:51
User entered 'No (N)'	System	07 Sep 2020 20:51:44

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:52:51
User entered 'No (N)'	System	07 Sep 2020 20:51:44

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:52:51
User entered 'No (N)'	System	07 Sep 2020 20:51:44

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:54:34
Un-reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 13:27:13
User entered 'Carlos' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 13:27:13
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 17:09:38
Amendment Manager: User entered empty.	System	14 Sep 2020 22:05:45
User entered 'Carlos'	(b) (4), (b) (6)	09 Sep 2020 00:08:03

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:54:34
Un-reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 13:27:13
User entered 'Fierro' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 13:27:13
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 17:09:38
Amendment Manager: User entered empty.	System	14 Sep 2020 22:05:45
User entered 'Fierro'	(b) (4), (b) (6)	09 Sep 2020 00:08:03

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:54:34
Un-reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 13:27:13
User entered '16300 College Blvd' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 13:27:13
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 17:09:38
Amendment Manager: User entered empty.	System	14 Sep 2020 22:05:45
User entered '16300 College Blvd'	(b) (4), (b) (6)	09 Sep 2020 00:08:03

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:54:34
User entered 'Shawnee'	System	25 Sep 2020 13:52:03
Un-reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 13:27:13
User entered 'Lenexa' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 13:27:13
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 17:09:38
Amendment Manager: User entered empty.	System	14 Sep 2020 22:05:45
User entered 'Lenexa'	(b) (4), (b) (6)	09 Sep 2020 00:08:03

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:54:34
User entered 'KS'	System	25 Sep 2020 13:52:03
Un-reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 13:27:13
User entered 'Kansas' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 13:27:13
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 17:09:38
Amendment Manager: User entered empty.	System	14 Sep 2020 22:05:45
User entered 'KS'	(b) (4), (b) (6)	09 Sep 2020 00:08:03

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:54:34
Un-reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 13:27:13
User entered '66219' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 13:27:13
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 17:09:38
Amendment Manager: User entered empty.	System	14 Sep 2020 22:05:45
User entered '66219'	(b) (4), (b) (6)	09 Sep 2020 00:08:03

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:56:00
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 02:00:46
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 17:09:38
User entered 'US' (non-conformant).	System	07 Sep 2020 20:52:56

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	25 Nov 2020 17:31:59
User entered '6'	System	10 Nov 2020 18:09:06
User entered '5'	System	10 Nov 2020 16:36:52
User entered '4'	System	07 Oct 2020 14:54:48
User entered '3'	System	25 Sep 2020 13:52:03
User entered '2'	System	17 Sep 2020 17:09:58
User entered '1'	System	07 Sep 2020 20:52:56

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:02:15

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:56:00
User entered '10/Nov/2020 11:36'	System	10 Nov 2020 16:36:52

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:02:15

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 18:08:57
User entered 'I'	(b) (4), (b) (6)	10 Nov 2020 16:36:52

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:52:51
User entered		
'USA-US300-2020-MRNA-1273-P301000002'	System	07 Sep 2020 20:51:44

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

Serious

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:52:51
User entered 'Yes (Y)'	System	07 Sep 2020 20:51:44

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:52:51
User entered 'No (N)'	System	07 Sep 2020 20:51:44

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:52:51
User entered 'No (N)'	System	07 Sep 2020 20:51:44

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:52:51
User entered 'Yes (Y)'	System	07 Sep 2020 20:51:44

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:52:51
User entered 'No (N)'	System	07 Sep 2020 20:51:44

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:52:51
User entered 'No (N)'	System	07 Sep 2020 20:51:44

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:52:51
User entered 'No (N)'	System	07 Sep 2020 20:51:44

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:54:34
Un-reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 13:27:13
User entered 'Carlos' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 13:27:13
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 17:09:38
Amendment Manager: User entered empty.	System	14 Sep 2020 22:05:45
User entered 'Carlos'	(b) (4), (b) (6)	09 Sep 2020 00:08:03

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:54:34
Un-reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 13:27:13
User entered 'Fierro' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 13:27:13
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 17:09:38
Amendment Manager: User entered empty.	System	14 Sep 2020 22:05:45
User entered 'Fierro'	(b) (4), (b) (6)	09 Sep 2020 00:08:03

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:54:34
Un-reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 13:27:13
User entered '16300 College Blvd' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 13:27:13
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 17:09:38
Amendment Manager: User entered empty.	System	14 Sep 2020 22:05:45
User entered '16300 College Blvd'	(b) (4), (b) (6)	09 Sep 2020 00:08:03

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:54:34
User entered 'Shawnee'	System	25 Sep 2020 13:52:03
Un-reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 13:27:13
User entered 'Lenexa' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 13:27:13
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 17:09:38
Amendment Manager: User entered empty.	System	14 Sep 2020 22:05:45
User entered 'Lenexa'	(b) (4), (b) (6)	09 Sep 2020 00:08:03

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:54:34
User entered 'KS'	System	25 Sep 2020 13:52:03
Un-reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 13:27:13
User entered 'Kansas' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 13:27:13
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 17:09:38
Amendment Manager: User entered empty.	System	14 Sep 2020 22:05:45
User entered 'KS'	(b) (4), (b) (6)	09 Sep 2020 00:08:03

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:54:34
Un-reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 13:27:13
User entered '66219' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 13:27:13
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 17:09:38
Amendment Manager: User entered empty.	System	14 Sep 2020 22:05:45
User entered '66219'	(b) (4), (b) (6)	09 Sep 2020 00:08:03

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:56:00
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 02:00:46
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 17:09:38
User entered 'US' (non-conformant).	System	07 Sep 2020 20:52:56

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	25 Nov 2020 17:31:59
User entered '6'	System	10 Nov 2020 18:09:06
User entered '5'	System	10 Nov 2020 16:36:52
User entered '4'	System	07 Oct 2020 14:54:48
User entered '3'	System	25 Sep 2020 13:52:03
User entered '2'	System	17 Sep 2020 17:09:58
User entered '1'	System	07 Sep 2020 20:52:56

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 17:02:15

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:56:00
User entered '10/Nov/2020 13:09'	System	10 Nov 2020 18:09:06

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 17:02:15

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:31:47
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:56:00
User entered 'I'	(b) (4), (b) (6)	10 Nov 2020 18:09:06

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:52:51
User entered		
'USA-US300-2020-MRNA-1273-P301000002'	System	07 Sep 2020 20:51:44

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

Serious

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:52:51
User entered 'Yes (Y)'	System	07 Sep 2020 20:51:44

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:52:51
User entered 'No (N)'	System	07 Sep 2020 20:51:44

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:52:51
User entered 'No (N)'	System	07 Sep 2020 20:51:44

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:52:51
User entered 'Yes (Y)'	System	07 Sep 2020 20:51:44

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:52:51
User entered 'No (N)'	System	07 Sep 2020 20:51:44

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:52:51
User entered 'No (N)'	System	07 Sep 2020 20:51:44

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 20:52:51
User entered 'No (N)'	System	07 Sep 2020 20:51:44

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:54:34
Un-reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 13:27:13
User entered 'Carlos' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 13:27:13
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 17:09:38
Amendment Manager: User entered empty.	System	14 Sep 2020 22:05:45
User entered 'Carlos'	(b) (4), (b) (6)	09 Sep 2020 00:08:03

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:54:34
Un-reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 13:27:13
User entered 'Fierro' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 13:27:13
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 17:09:38
Amendment Manager: User entered empty.	System	14 Sep 2020 22:05:45
User entered 'Fierro'	(b) (4), (b) (6)	09 Sep 2020 00:08:03

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:54:34
Un-reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 13:27:13
User entered '16300 College Blvd' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 13:27:13
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 17:09:38
Amendment Manager: User entered empty.	System	14 Sep 2020 22:05:45
User entered '16300 College Blvd'	(b) (4), (b) (6)	09 Sep 2020 00:08:03

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:54:34
User entered 'Shawnee'	System	25 Sep 2020 13:52:03
Un-reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 13:27:13
User entered 'Lenexa' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 13:27:13
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 17:09:38
Amendment Manager: User entered empty.	System	14 Sep 2020 22:05:45
User entered 'Lenexa'	(b) (4), (b) (6)	09 Sep 2020 00:08:03

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:54:34
User entered 'KS'	System	25 Sep 2020 13:52:03
Un-reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 13:27:13
User entered 'Kansas' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 13:27:13
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 17:09:38
Amendment Manager: User entered empty.	System	14 Sep 2020 22:05:45
User entered 'KS'	(b) (4), (b) (6)	09 Sep 2020 00:08:03

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:56:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 14:54:34
Un-reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 13:27:13
User entered '66219' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 13:27:13
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 17:09:38
Amendment Manager: User entered empty.	System	14 Sep 2020 22:05:45
User entered '66219'	(b) (4), (b) (6)	09 Sep 2020 00:08:03

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:56:00
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 02:00:46
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 17:09:38
User entered 'US' (non-conformant).	System	07 Sep 2020 20:52:56

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:02:15

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	25 Nov 2020 17:31:59
User entered '6'	System	10 Nov 2020 18:09:06
User entered '5'	System	10 Nov 2020 16:36:52
User entered '4'	System	07 Oct 2020 14:54:48
User entered '3'	System	25 Sep 2020 13:52:03
User entered '2'	System	17 Sep 2020 17:09:58
User entered '1'	System	07 Sep 2020 20:52:56

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 17:02:15

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered '25/Nov/2020 12:31'	(b) (4) System	25 Nov 2020 17:31:59

US3312212

Folder: SAE USA-US300-2020-MRNA-1273-P301000002

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 17:02:15

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:21:29
User entered 'I'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:31:59